infoEd

CTMS

User Manual

For Clinical Trial Research Management Coordinators and Trial Staff

NYU Langone Medical Center

Research IT
Last Updated 3/10/11

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Important addresses and phone numbers:	
InfoEd System URL:	http://infoed.med.nyu.edu
MCIT Self-Service URL:	http://nyumc.net/nyu/mcit
OCT (Office of Clinical Trials)	212.263.4210

Logging In

InfoEd can be reached only via the NYU Langone Medical Center network. That means you need to be on-site, or have VPN access to reach the NYU network remotely.

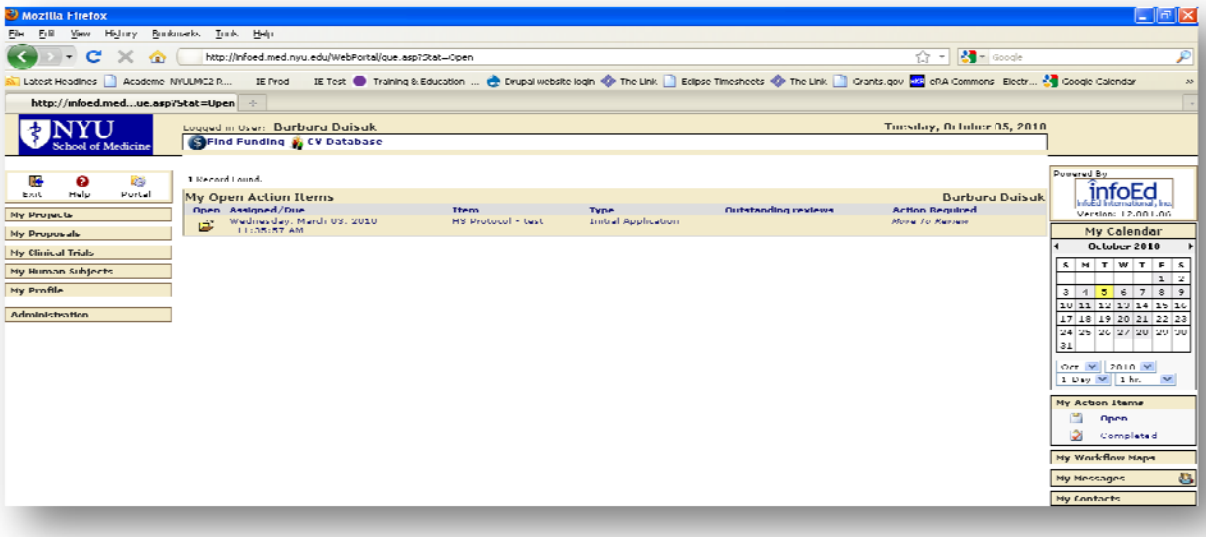
> **Tip**: Access MCIT Self-Service via the link above to submit a request for an InfoEd Remote Access Quick Reference. The guide describes how to set up off-campus access through OnSiteHealth.

InfoEd Production

- The InfoEd server's address is: http://infoed.med.nyu.edu
- To log in, enter your **Kerberos ID** and your **InfoEd password**.

Screen Orientation

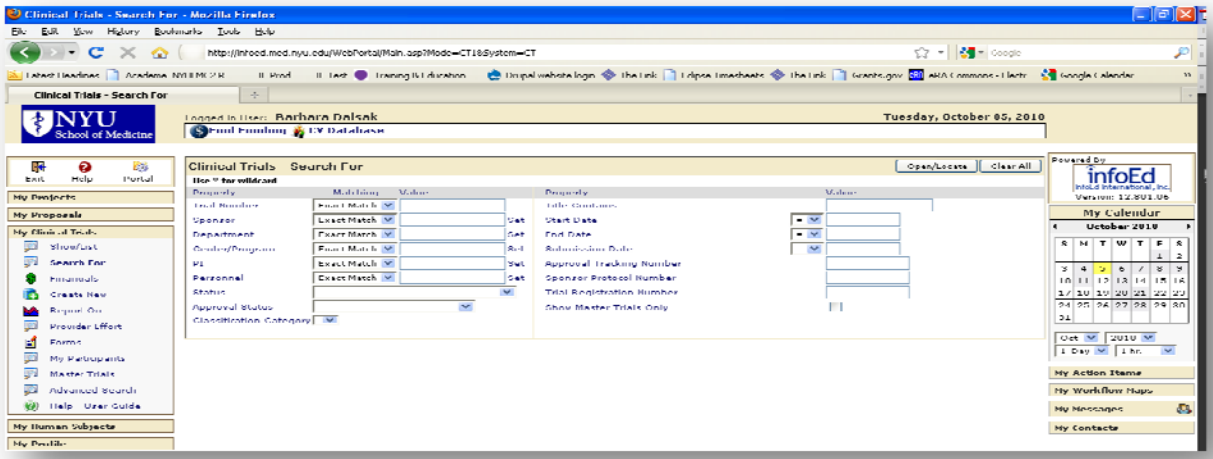
Immediately after logging in, your CTMS screen will look like below. **Note**: Your left Navigation Tool Bar options will vary based on what modules to which you have access.



- Immediately after Logging In, you will click on My Clinical Trials.

Locating and Opening a Study in CTMS

- Click on the Search For screen.



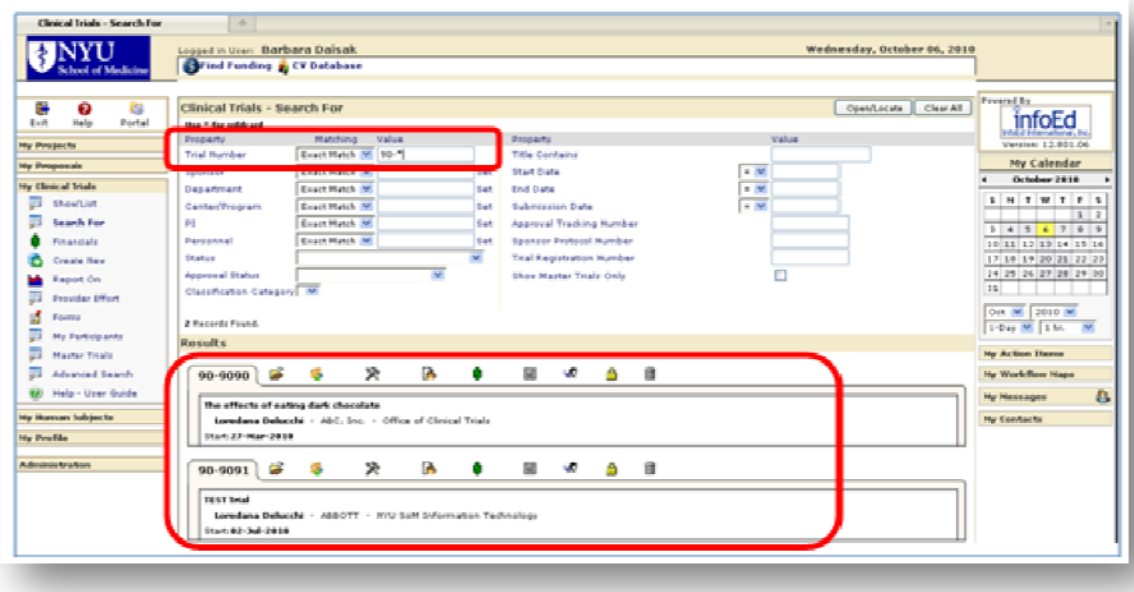
There are several options for finding a study in CTMS. This section describes all of the searching options that are available to you.

- The first and most direct way is to enter the Research Number for the study in the "Trial Number" field.
- The second way is to search by PI.
- The third way is to search by PI and Sponsor.

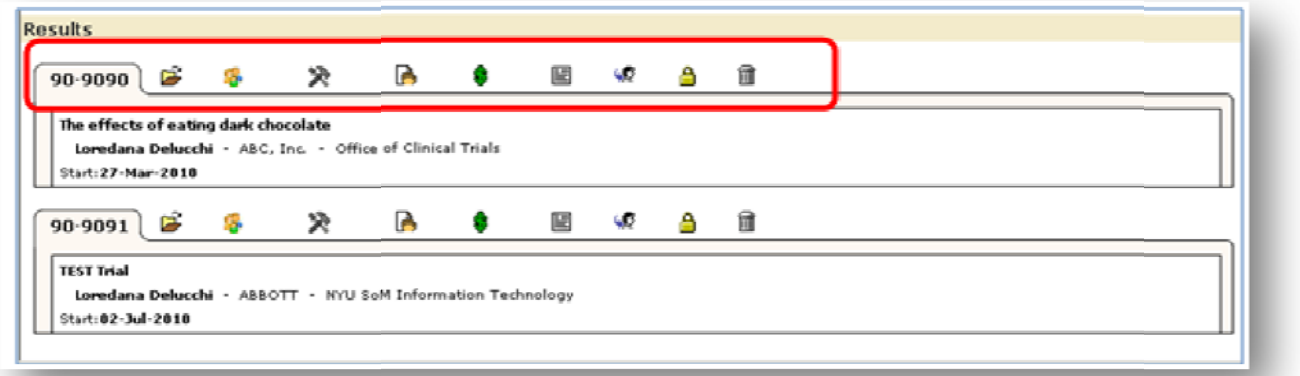
Locating Study by Trial Number

- Type the Research Number into the Trial Number field.
- Click **Open/Locate**.

  Note: Wildcard Searches. You should use an asterisk (*) to denote a wildcard at the end of your search. For instance, if you're looking for all studies that start with the trial number "07-1" you would type "07- 1*" in the search value field.
- The results appear below the main search area.



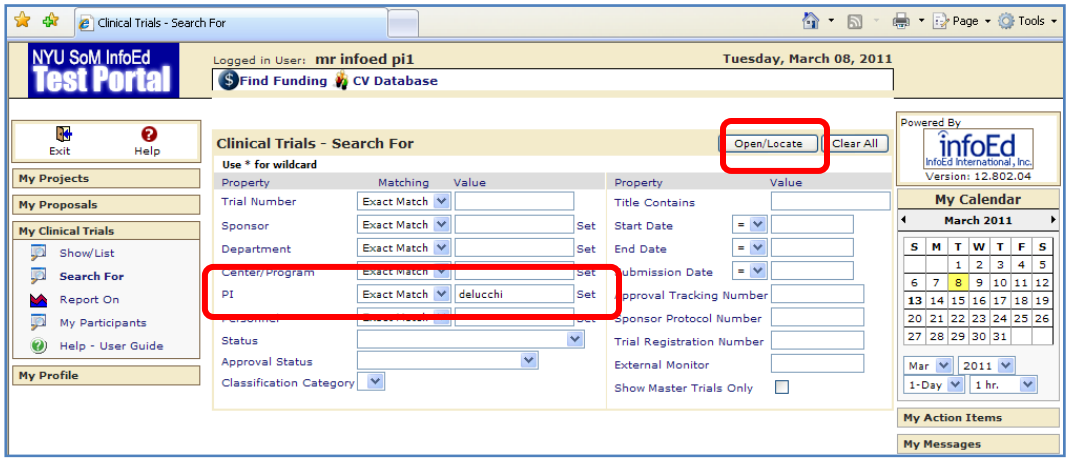
Trial Icons. The icons to the right of the trial number are the **Trial Icons**. Depending on your level of access, some of them may be grayed out indicating that the function is not available to you. Specifically, the delete trash icon is normally not available to non-module administrators.



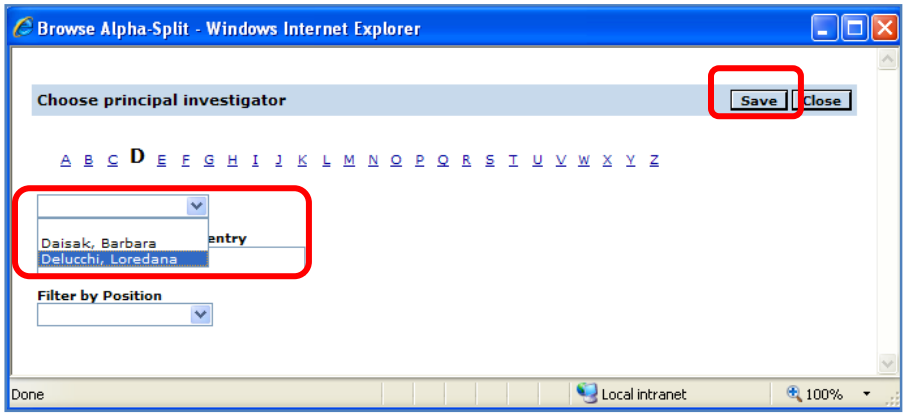
- If you do not enter the exact **Trial Number**, you will get a results list of every study whose Trial Number is a partial match to what you entered.

Locating a Study by PI Name

- Type the last name of the PI into the **PI** field, such as “delucchi”
- Press the **Open/Locate** button.

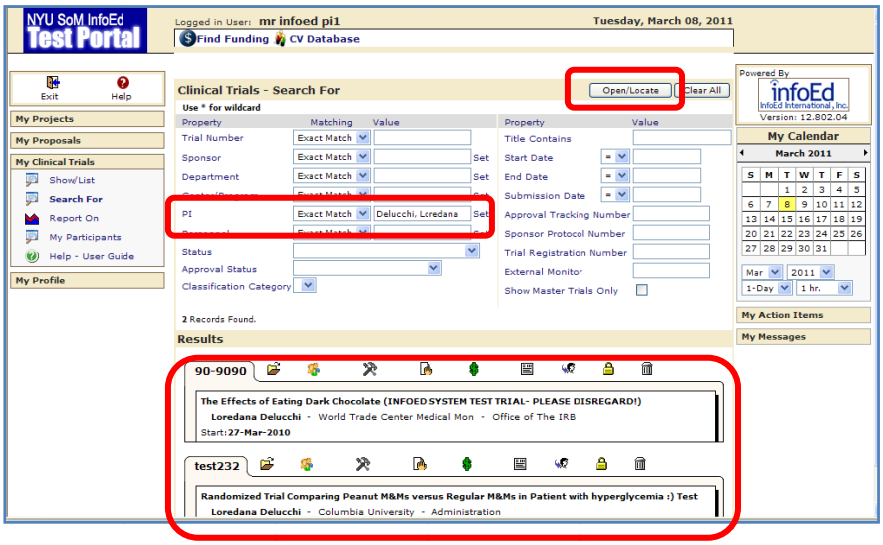


- If you do not know the exact spelling of the PI's name, you can instead look the name up.
- Click the **Set** button to the right of **PI** field. This will pop open a new window where you can find the PI by their last name.
- Click on the **first letter** of the PI's last name, such as "**D**" for "**Delucchi**."


Browse Alpha-Split - Windows Internet Explorer
Choose principal investigator
Save
Close
A B C D E F G H I J K L M N O P Q R S T U V W X Y Z
Daisak, Barbara
Delucchi, Loredana
Filter by Position
Done
Local intranet
100%

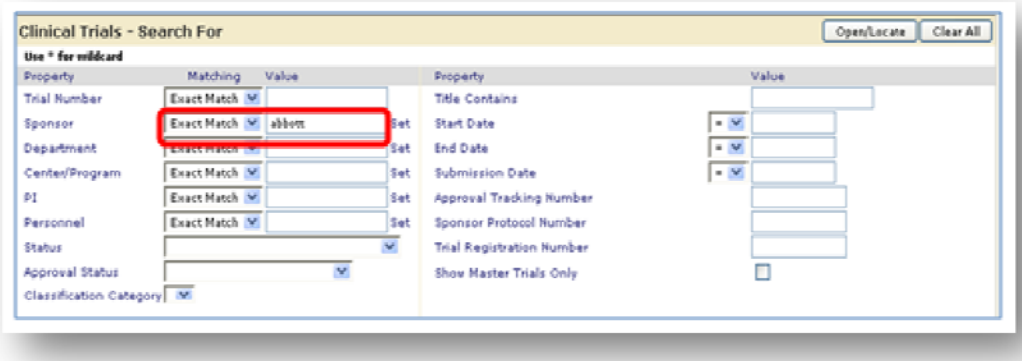
- Select the investigator name from the **Investigator** drop-down menu.
- Click the **Save** button.

- Click the **Open/Locate** button. The search results will display all the studies where the person selected is the PI.
- Scroll through the search results to locate the desired study to open.

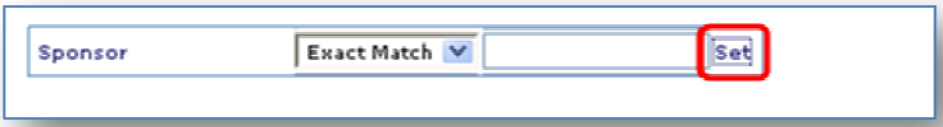


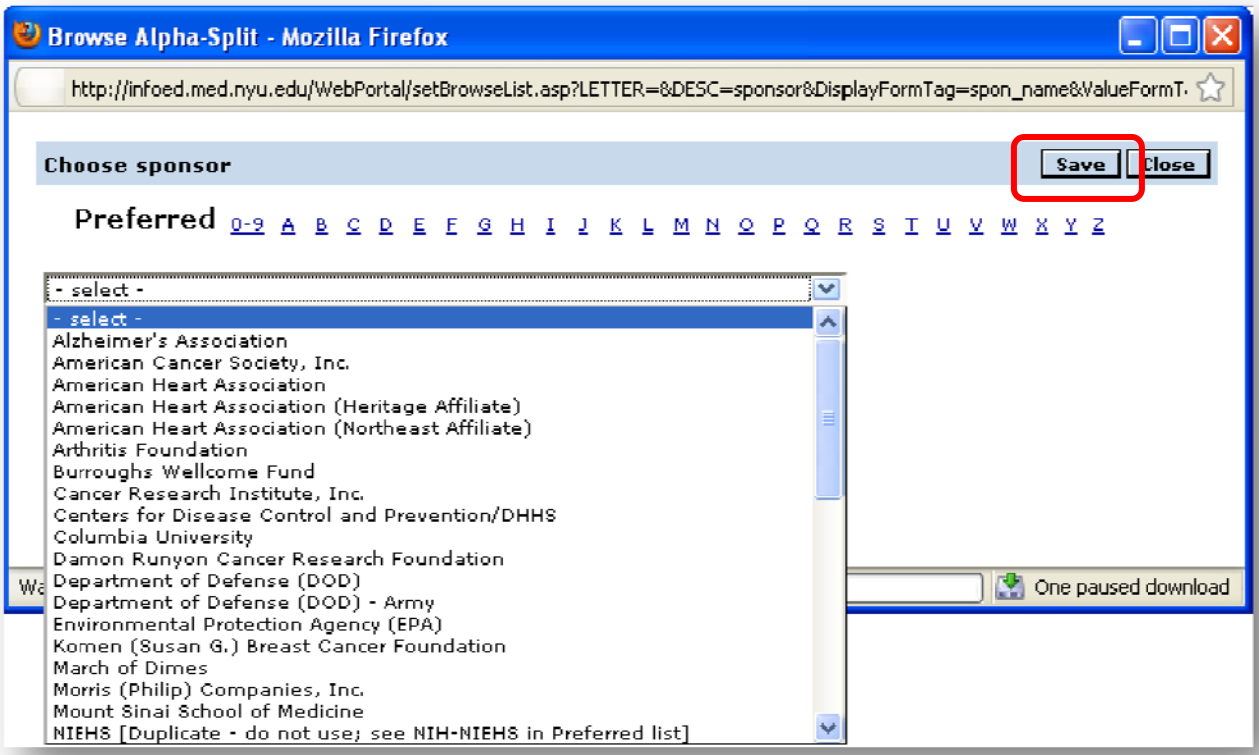
Locating a Study by Sponsor

- Type the exact name of the sponsor in the **Sponsor** field… or



- To the right of the Sponsor field, press **Set** to look up the sponsor's name using an alphabetical pick-list window.



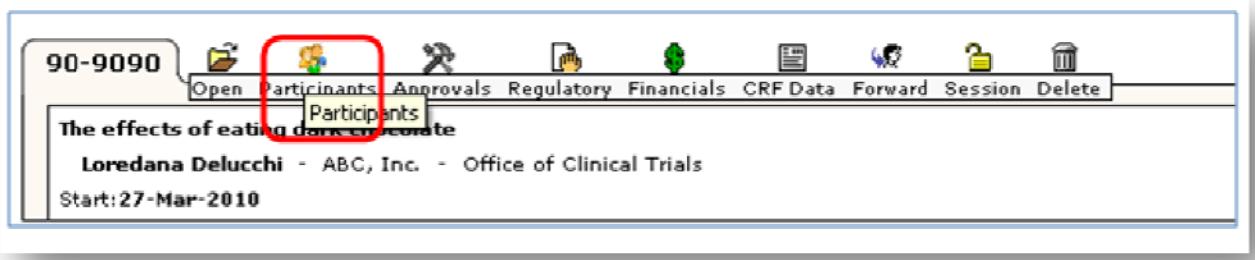

Browse Alpha-Split - Mozilla Firefox
http://infoed.med.nyu.edu/WebPortal/setBrowseList.asp?LETTER=&DESC=sponsor&DisplayFormTag=spon_name&ValueFormT
Choose sponsor
Save
Close
Preferred 0-9 A B C D E F G H I J K L M N O P Q R S T U V W X Y Z
- select -
- select -
Alzheimer's Association
American Cancer Society, Inc.
American Heart Association
American Heart Association (Heritage Affiliate)
American Heart Association (Northeast Affiliate)
Arthritis Foundation
Burroughs Wellcome Fund
Cancer Research Institute, Inc.
Centers for Disease Control and Prevention/DHHS
Columbia University
Damon Runyon Cancer Research Foundation
Department of Defense (DOD)
Department of Defense (DOD) - Army
Environmental Protection Agency (EPA)
Komen (Susan G.) Breast Cancer Foundation
March of Dimes
Morris (Philip) Companies, Inc.
Mount Sinai School of Medicine
NIEHS [Duplicate - do not use; see NIH-NIEHS in Preferred list]
One paused download

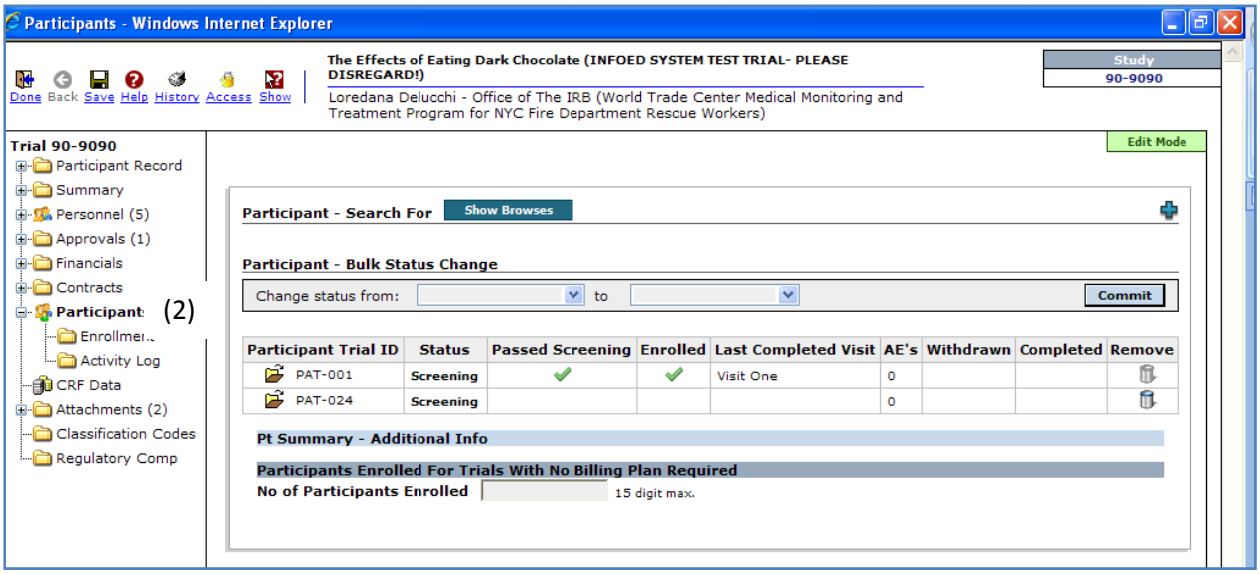
- Once you've found the sponsor, press the **Save** button (closing the sponsor pick-list window) and then press the **Open/Locate** button to display a list of all studies with that sponsor.

Opening a Study to Find the Participants Section

For this manual, we will work with study **90-9090**. When you hover over the toolbar, screen tips will list the icon function.

- Click the **Participants** icon to begin entering Participants. This causes a new window to open above our main CTMS search screen.





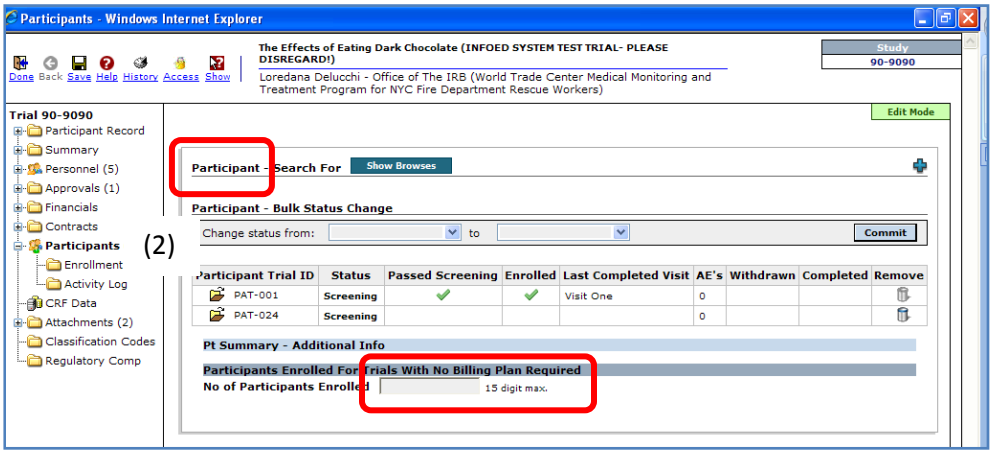
Entering Participants

> **Important**: Contact your Assigned RMC from OCT (Office of Clinical Trials) to determine if you need to enter the Number of Participants Enrolled or enter Study Participants individually as below.

Entering the Number of Participants for Studies with No Billing Plan Required

Follow the steps below for **studies with No Billing Plan Required**, such as for survey or registry studies.

- On the **Participants** screen Participants Enrolled for Trials With No Billing Plan Required box, No. of Participants Enrolled box, type the correct Number of Participants Enrolled**.**



Adding a New Participant in the Participants Section

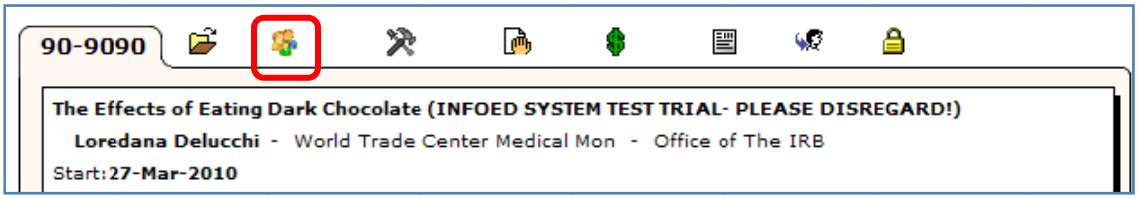
Add new participants, when the Trial Status is **Open for Enrollment**.

See the **Appendix** section that describes what needs to be completed in order to add Participants.

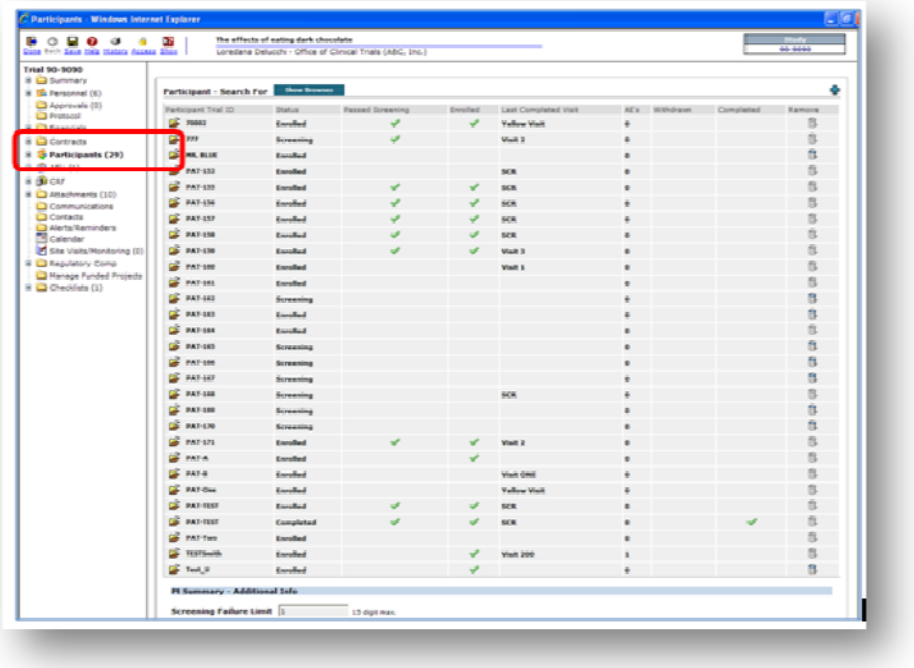
This option is located via the Trial **Summary** screen. Click on the Summary option to view the trial status.

- Refer to the **Appendix** section for the required fields before adding your participants.

- Click the **Participants** icon to begin entering Participants.
  This causes a new window to open above our main CTMS search screen.


90-9090
The Effects of Eating Dark Chocolate (INFOED SYSTEM TEST TRIAL- PLEASE DISREGARD!)
Loredana Delucchi - World Trade Center Medical Mon - Office of The IRB
Start:27-Mar-2010

- On the left navigation bar, the **Participants** folder is bolded.
  The Participants Screen displays listing Participants already entered into the trial.

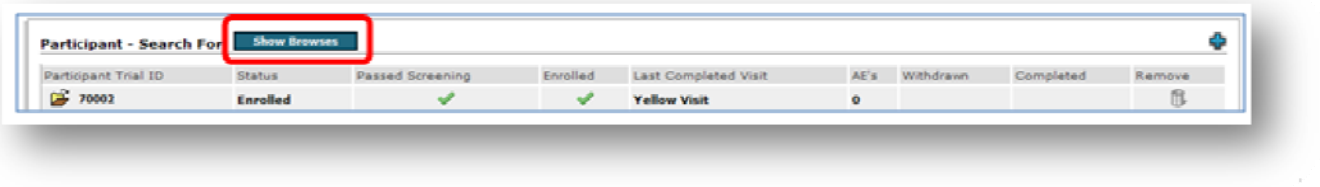


To Search for a Participant Name within the Specific Trial's List of Participants

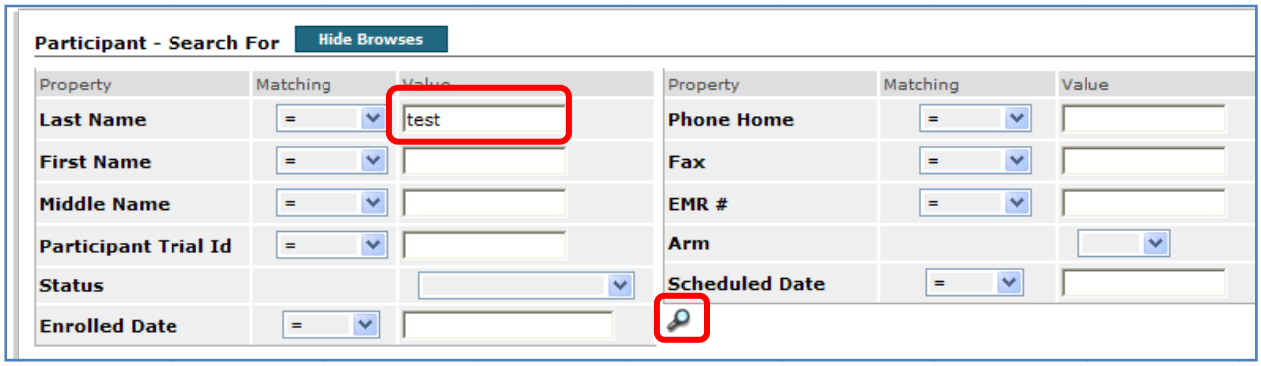
Once you have selected a specific Trial number, you will see the Participants Folder in the Left Navigation Tool bar (above circled in red).

To add a Participant, start by doing the following:

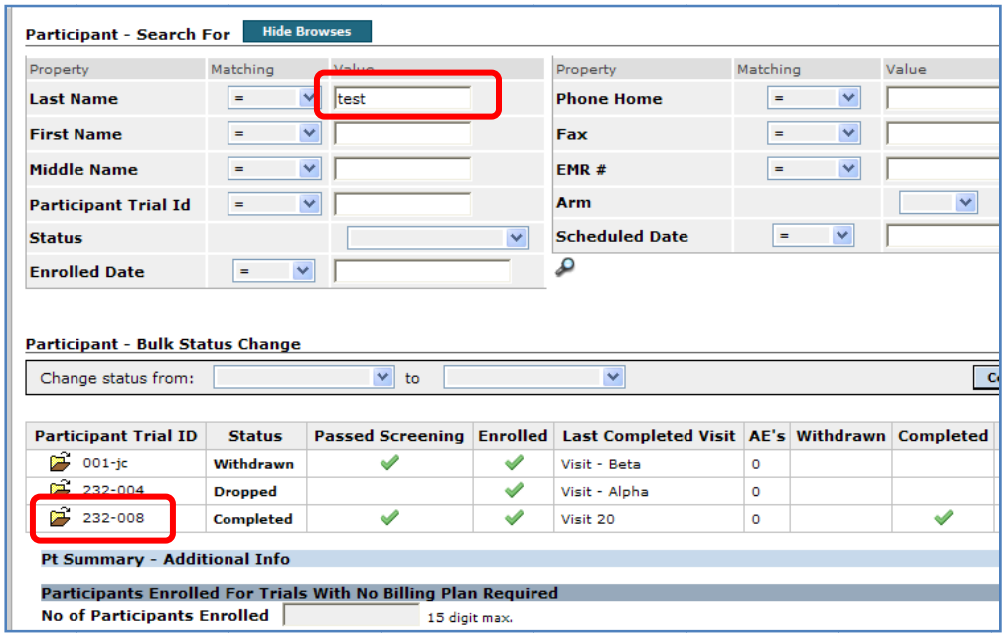
1. Check to see if this person's name is already entered within the trial **to avoid duplicate data entry**.
   a. To verify if your Participant is already in the Trial, click **Show Browses**



b. Type the desired Participant name in the Last Name field.

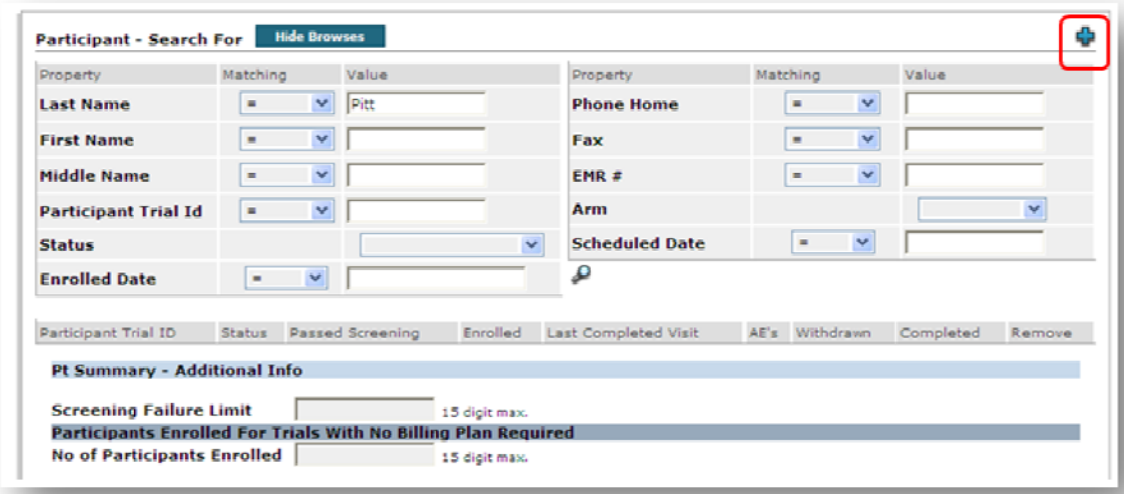


c. Click the folder to view enter additional Participant information.

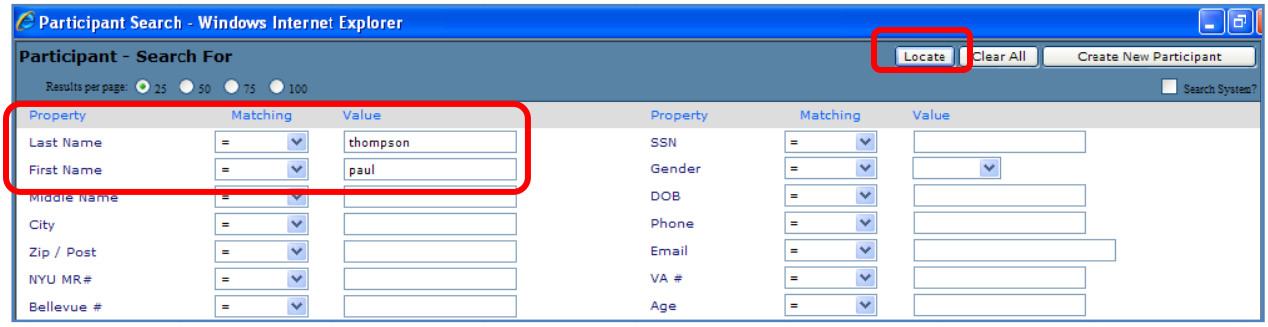


If the Participant is found, skip to the Entering Participant Information section.

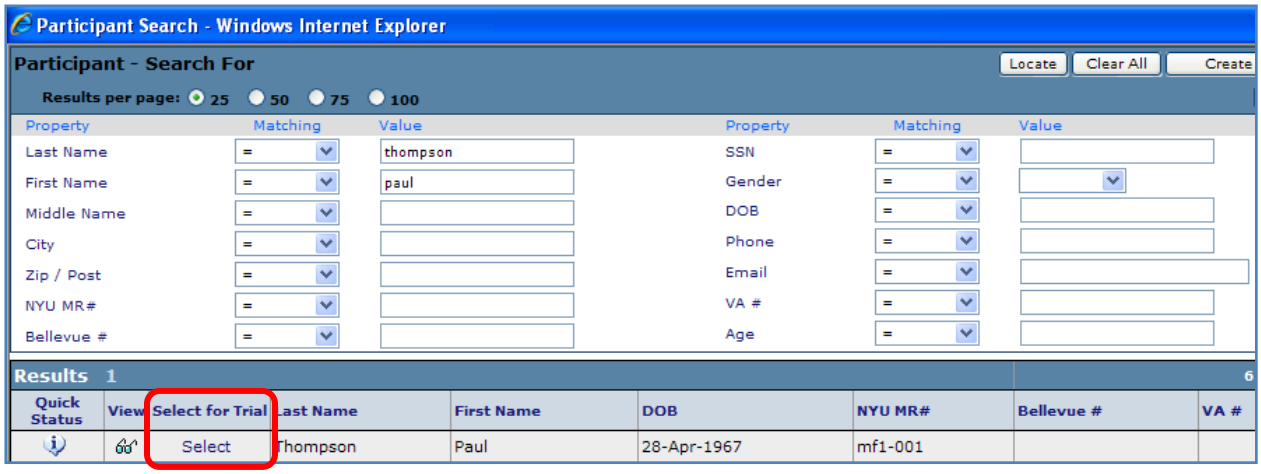
If the name is not in the Trial, please check to see if the person is associated with another Trial and has his/her name already listed within the listing of all Participants in the CTMS Participants Directory in the Infoed System by clicking on the Plus Icon .



1. Now enter the person's **Last Name** and **First Name** into the corresponding fields:



If you find any results, they will be listed under the Search For section in the **Results** Subsection and you can view the result by clicking on the **Select** hyperlink.

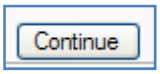


In the Identify Participants Pool window, the **Trial Pool 90-9090** checkbox is automatically selected.
This indicates that the found Participant is automatically added to the trial pool.

For example:

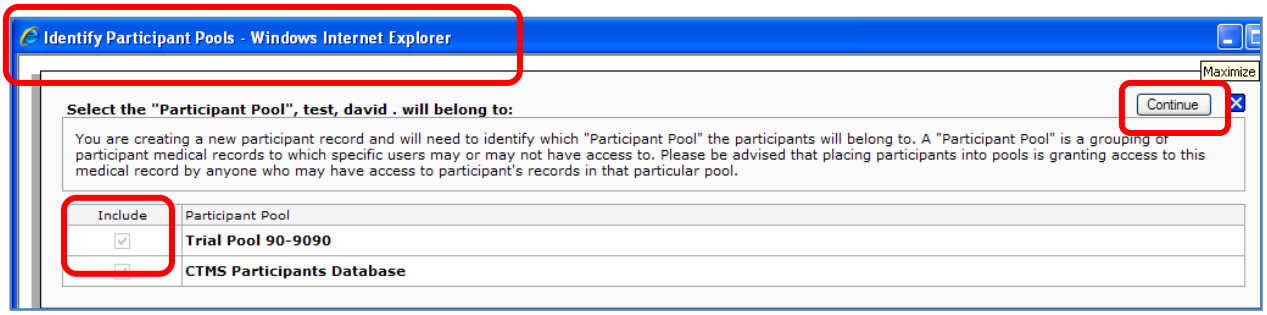
☑ Trial Pool 90-9090
☑ CTMS Participants Database

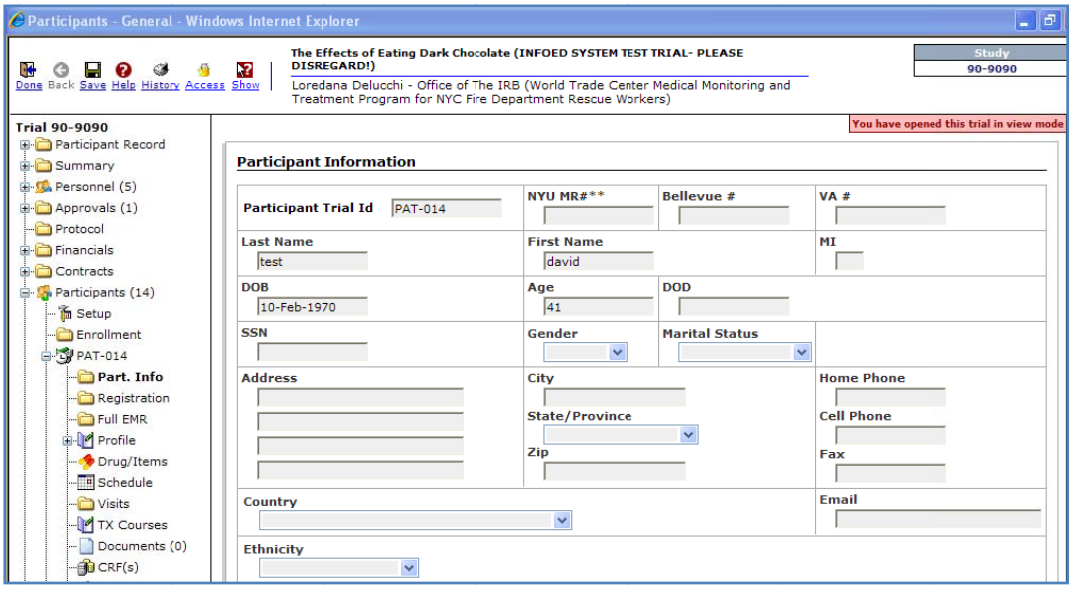
Indicates that the Participant is automatically added to the Trial Pool and is retrieved from the CTMS Participants Database.

2. Click **Continue**. 

The **Partipant's Information** screen displays.

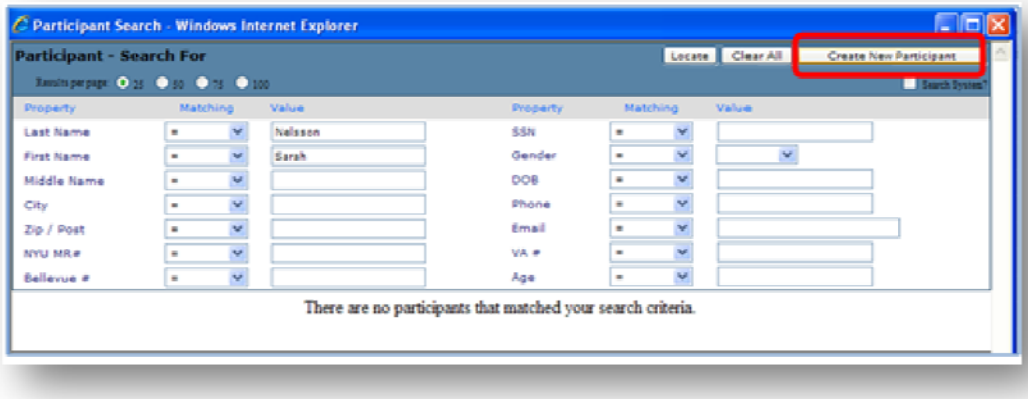
Refer to the Entering Participants information section of this User Guide.


Identify Participant Pools - Windows Internet Explorer
Maximize
Continue
Select the "Participant Pool", test, david . will belong to:
You are creating a new participant record and will need to identify which "Participant Pool" the participants will belong to. A "Participant Pool" is a grouping of participant medical records to which specific users may or may not have access to. Please be advised that placing participants into pools is granting access to this medical record by anyone who may have access to participant's records in that particular pool.
Include
Participant Pool
Trial Pool 90-9090
CTMS Participants Database

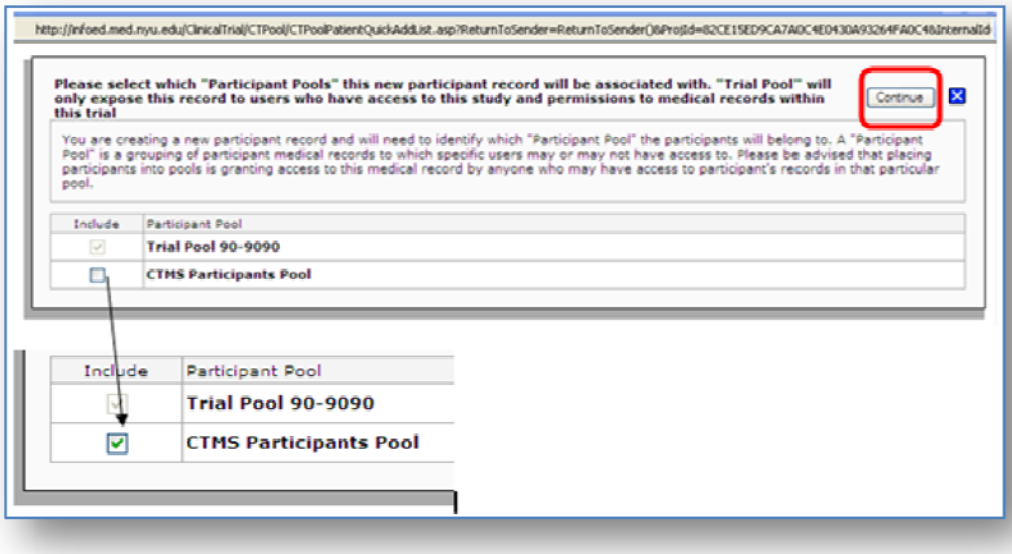


Adding a New Participant (one not already in the CTMS Participant Database)

If the Participant is not found, click **Create New Participant**.



Click the **NYU Patients** checkbox to add the patient to the CTMS Participant Database for entry into future research trials.

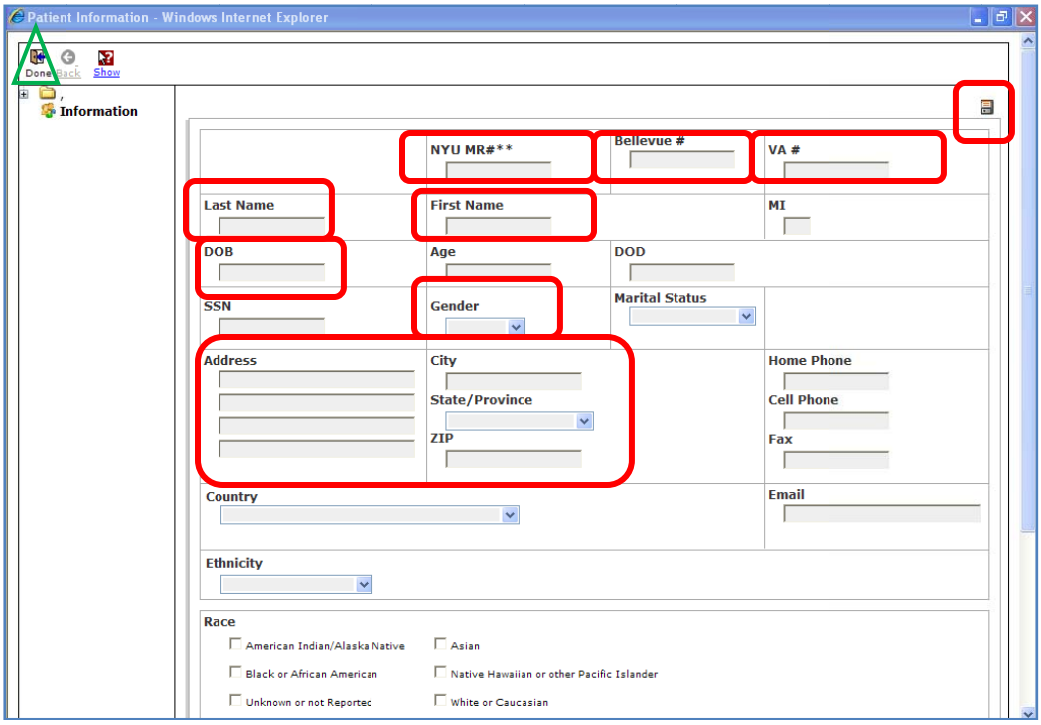

Please select which "Participant Pools" this new participant record will be associated with. "Trial Pool" will only expose this record to users who have access to this study and permissions to medical records within this trial
Continue
You are creating a new participant record and will need to identify which "Participant Pool" the participants will belong to. A "Participant Pool" is a grouping of participant medical records to which specific users may or may not have access to. Please be advised that placing participants into pools is granting access to this medical record by anyone who may have access to participant's records in that particular pool.
Include
Participant Pool
Trial Pool 90-9090
CTMS Participants Pool

Check off the box to Include **CTMS Participants Pool**.
Click **Continue** in the upper right corner. The window will close.

In the new window that opens, complete the **Participant** information.

The following patient details are required.

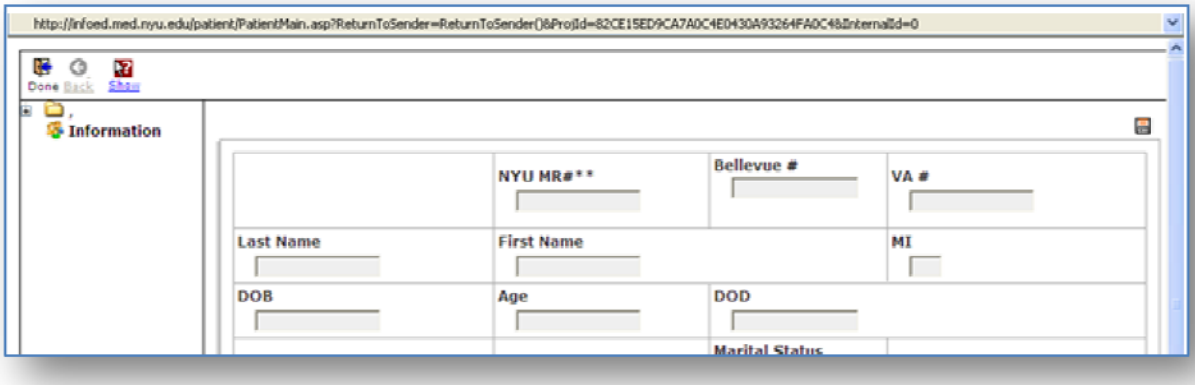
- ***NYU MR# or Bellevue # or VA# (circled in light blue below) is required if it is known.***
- Participant First and Last Name and Middle initial.
- Date of Birth (DOB)
- Gender
- Full Address, City, State, Zip
- Additional optional Patient Information can be added here as per department policy. For example, Radiology may enter Ethnicity and Race.



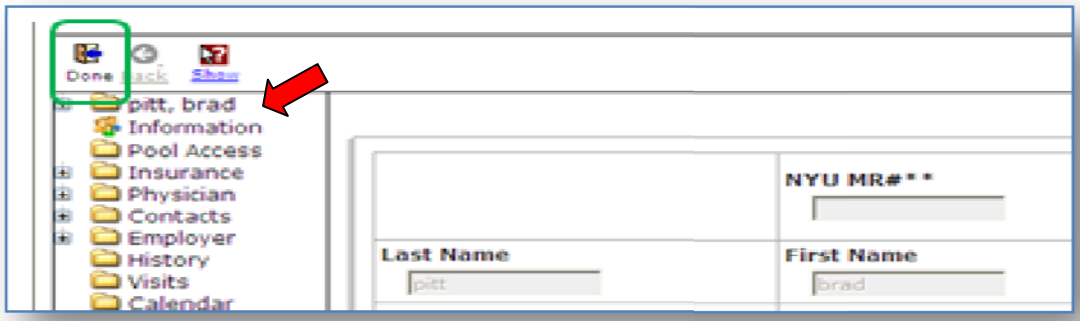
1. In the upper right corner, click **Save.**

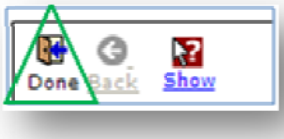
   Notice the changes in the Left Navigation Tool Bar area:

   Before entering the information about the Participant, there is no name in this field.



After clicking on the **SAVE** button, the name of the Participant appears here.
An **EMR** (Electronic Medical Record) is created.

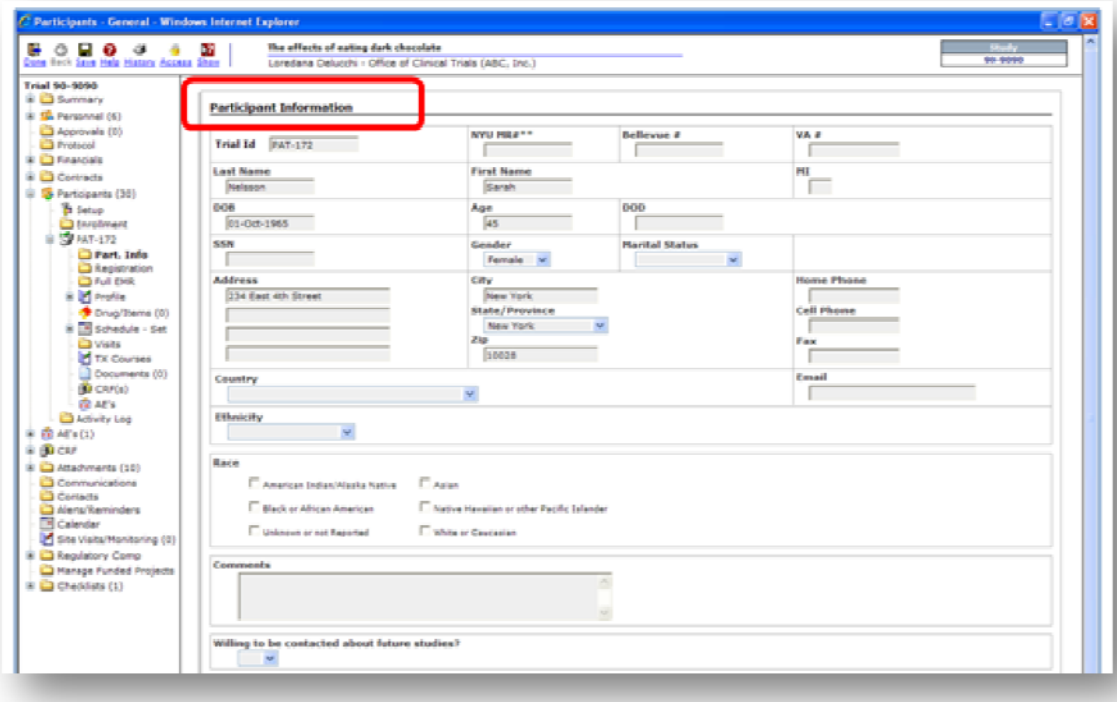




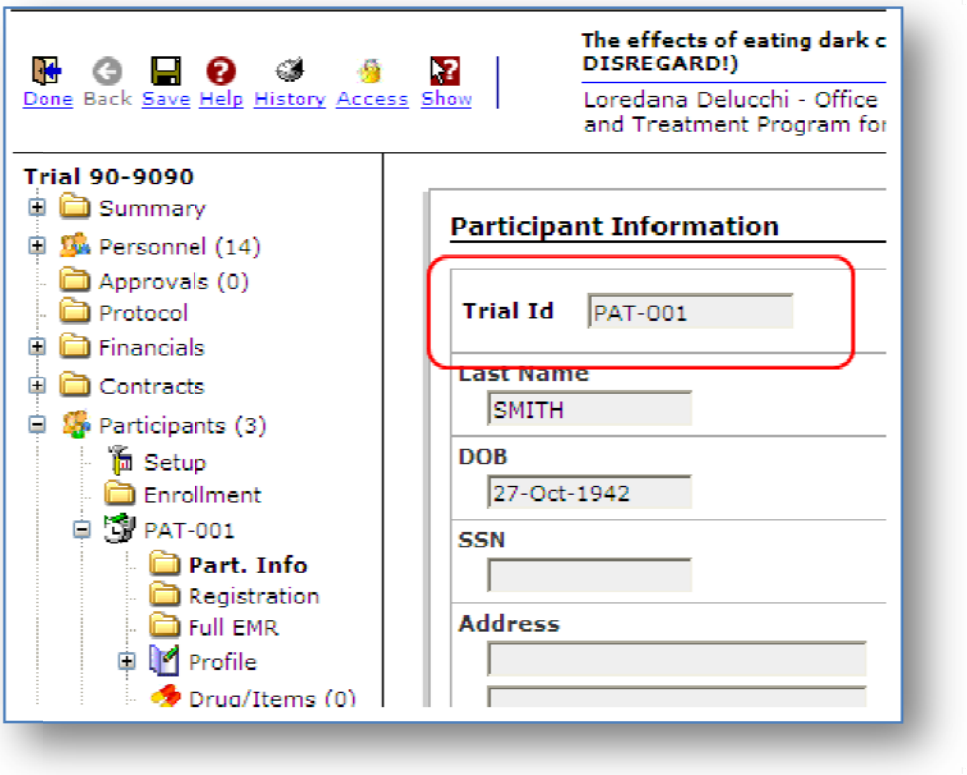
2. In the upper left-hand corner, click **Done** to exit this screen.

Entering Participant Information

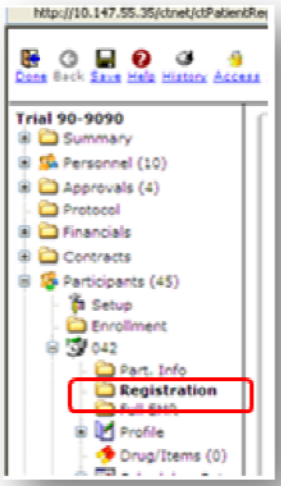
The new Participant is now added and you are returned to the Trial Folder view and the new Participant Information screen.



1. If you wish to edit the Trial ID assigned by the Infoed system, delete the PAT # that is there and assign the Trial ID relevant to your Trial for that Participant; it is a unique identifier.



2. Click **Save**
3. Next open the Registration folder

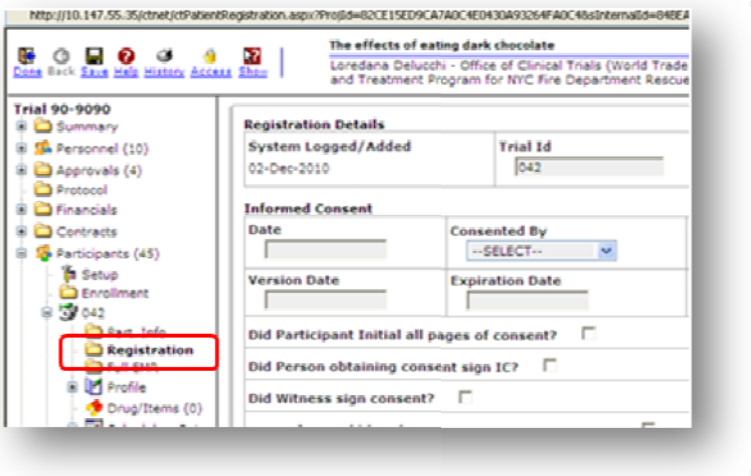


Now you are ready to enter the Registration information.

Registration Details for a Specific Participant

You are still in the participant's record.

1. Click on the **Registration** screen in the left navigation tool bar within the same participant for which you have been entering data :



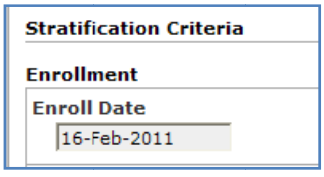
2. Type the record details of the Participant's registration process as required below:

   Make sure the **Trial ID** is correct or edit if necessary.

   a. Type the **Informed Consent Date**

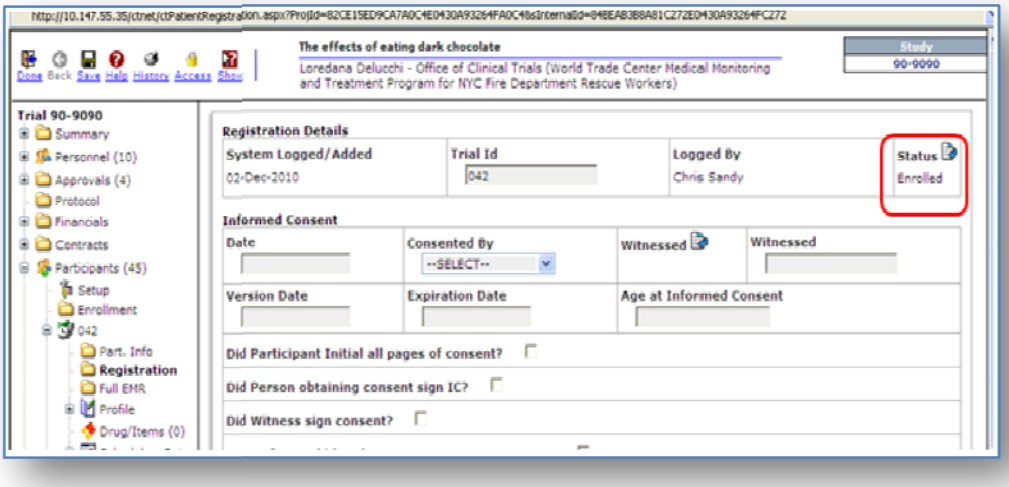
   b. Scroll and type the **Eligibility Date**

   c. Continue scrolling and type the **Enrollment Date**.



d. In the upper left corner, click **Save**.

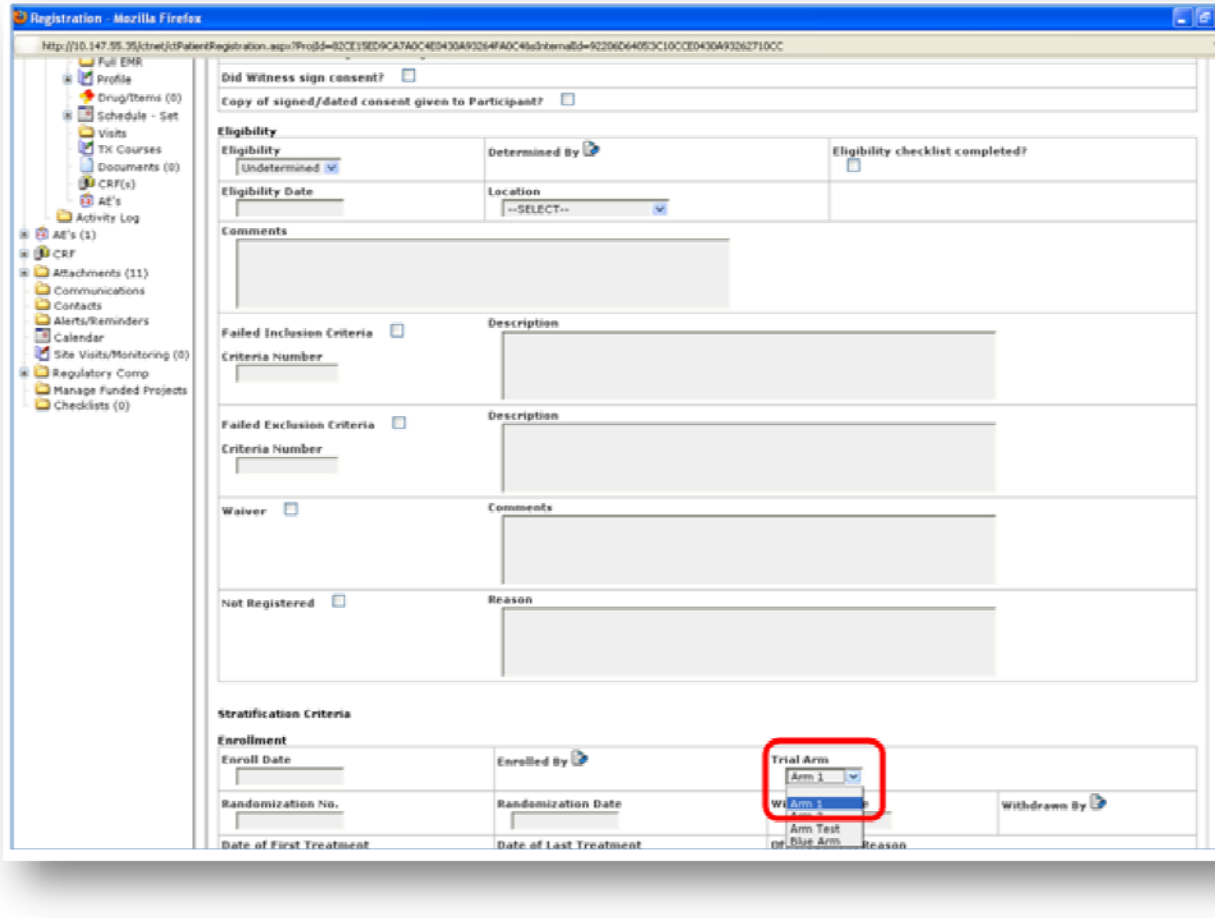
The Status automatically changes to Enrolled.

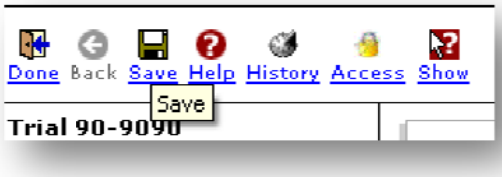


3. The **arm** must be identified also.
   a. Click the Trial Arm drop-down arrow and select the correct **Trial Arm**, such as **Arm 1.**
   b. Click **Save.**

Important: The OCT RMC must be contacted for any changes to the arms, cycles, visits, and procedures.

The Financials>Procedure matrix has all of the visits and procedures for the trial.
Trial **Arms** are treatment groups in a trial.
Arms contain **Cycles**, such as **Screening**.
Cycles contain **Visits**.
Visits contain **Procedures** or services performed on each visit.





- In the upper left-hand corner, click **Save**.

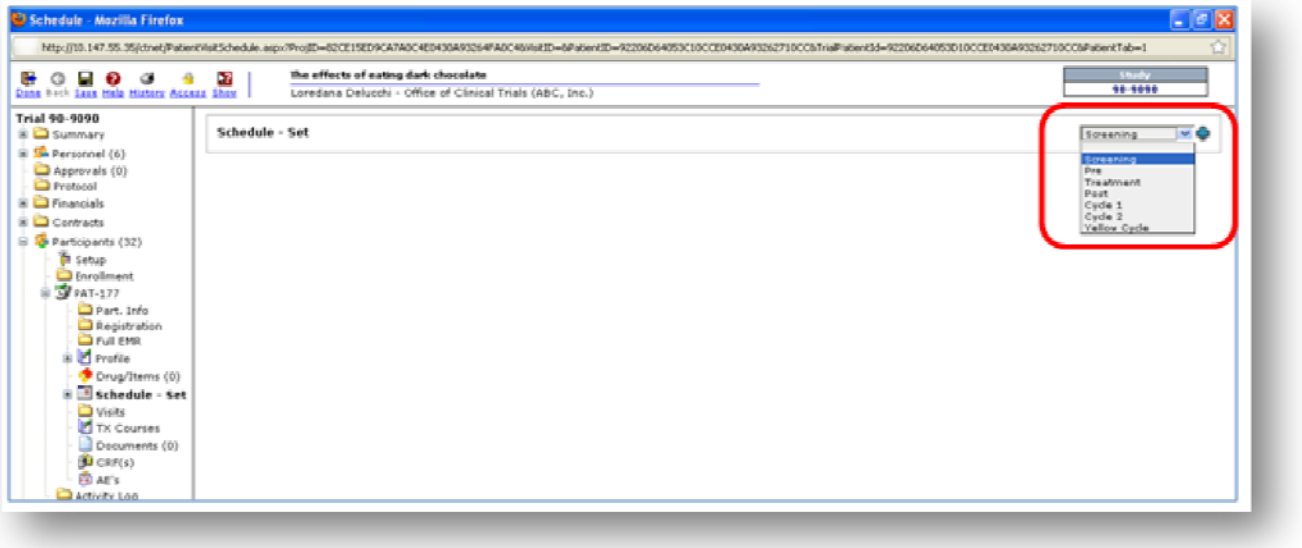
Adding a Visit

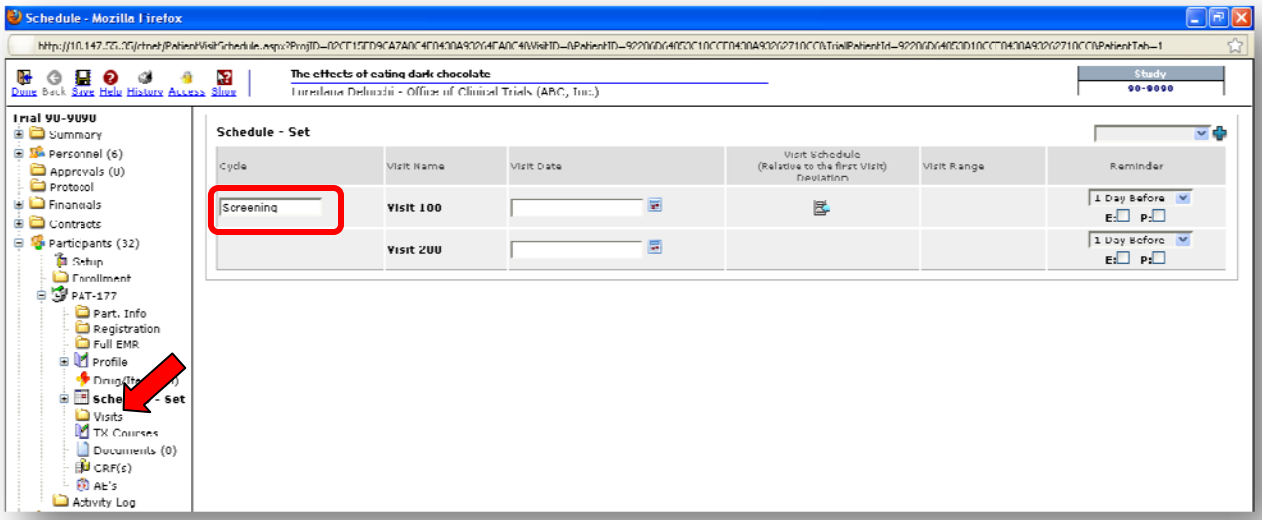
Schedule Set

The **Schedule Set** screen is where you assign visits to a participant by selecting one or more cycles from the pull-down menu and then pressing the add **(+)** icon.

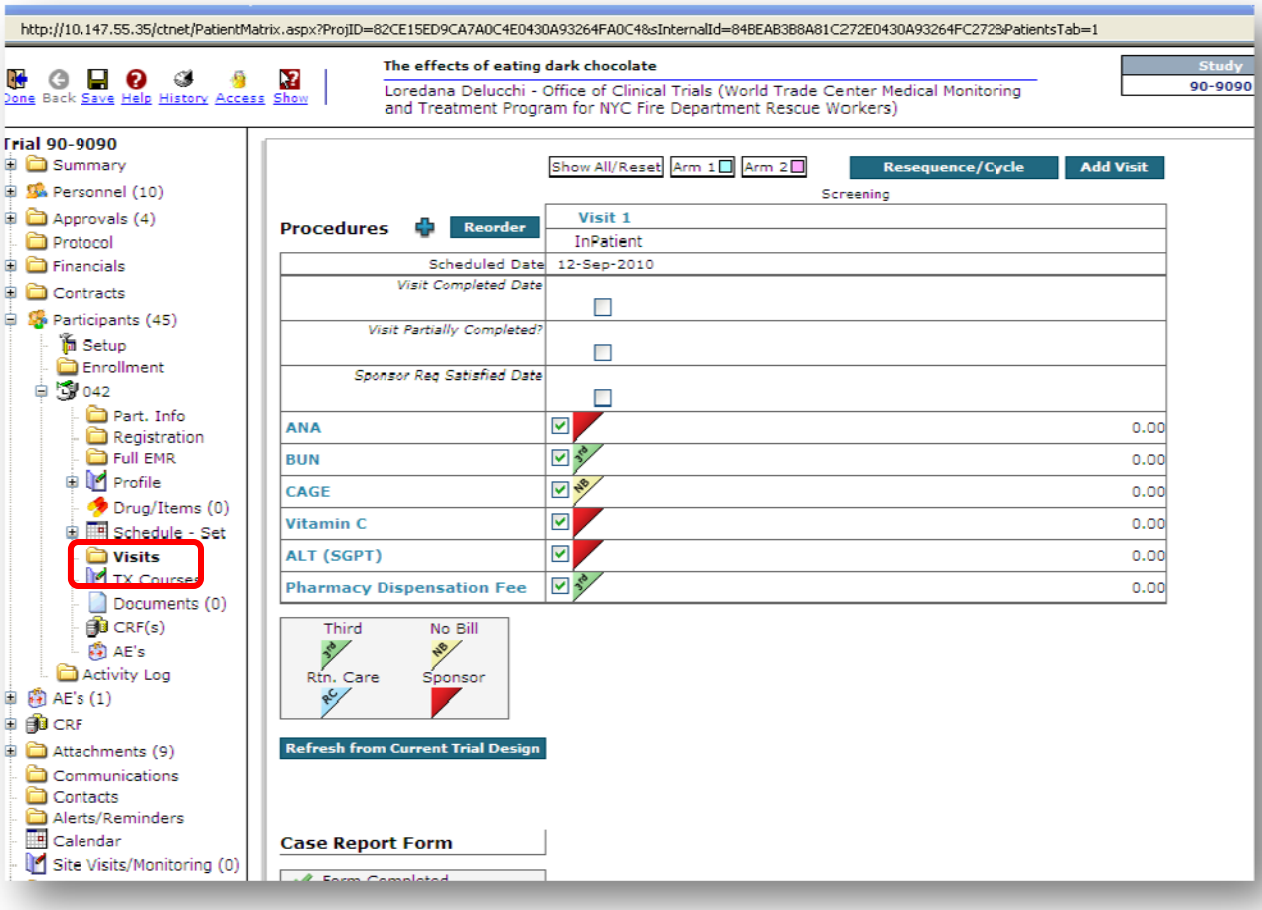
- In the left-hand navigation menu, find and click **Schedule – Set**.
- Click the drop-down arrow and select the desired cycle, such as **Screening**.
- Click to add the cycle.
  This will add all of the visits that have been assigned to that cycle.

  Only add cycles as the participant goes through them.





- Click on the **Visits** folder to continue.



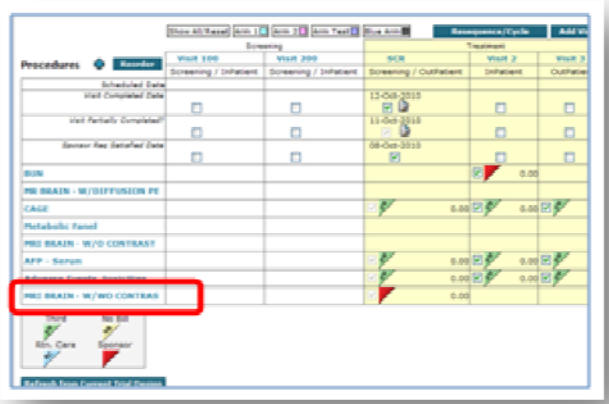
Procedure Functions

Multiple Providers

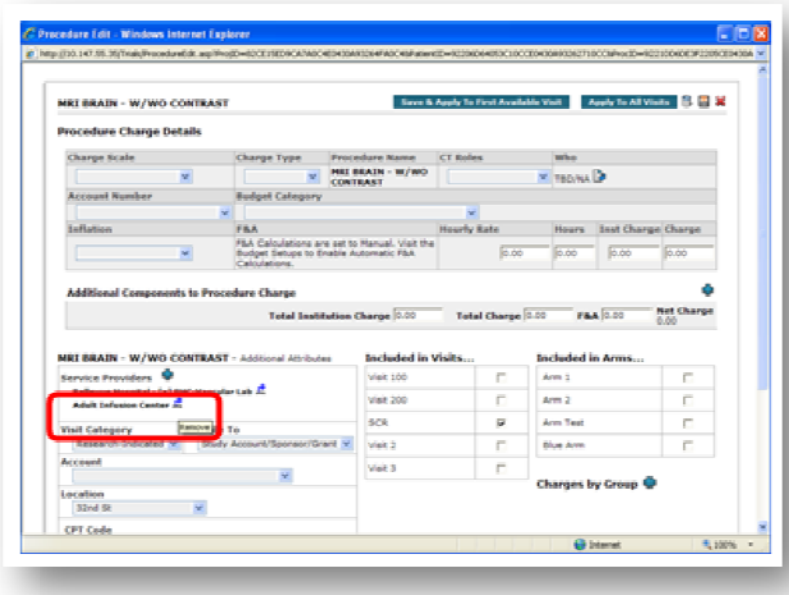
Delete a Provider

If Multiple Providers list on an Encounter Report Ticket, delete the additional or incorrect provider name(s).

- Click on the procedure name, such as **MRI BRAIN – W/WO CONTRAS.**

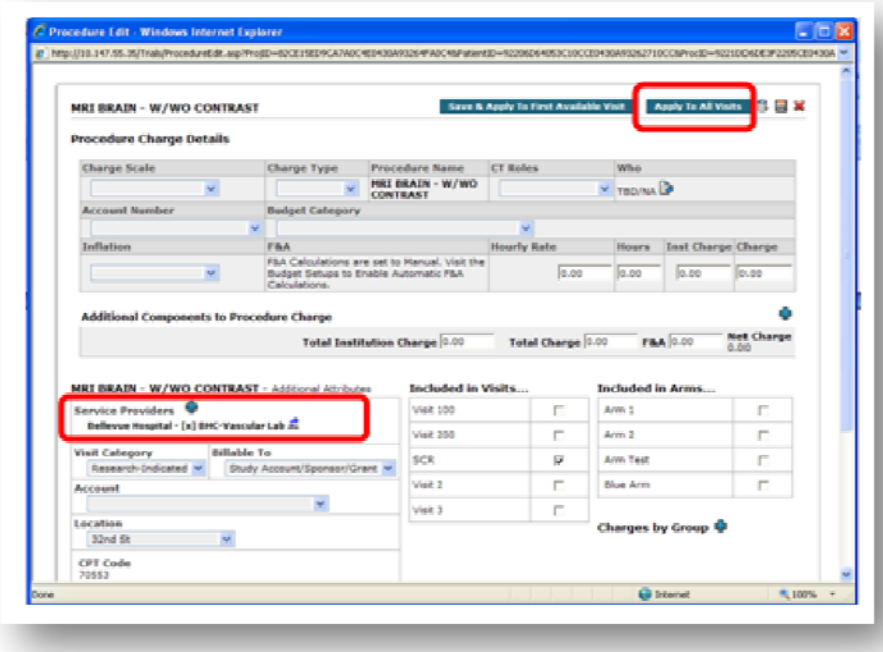


- To remove an incorrect or additional provider, click the **Remove** arrow to the right of the desired provider name.



Only one provider displays.

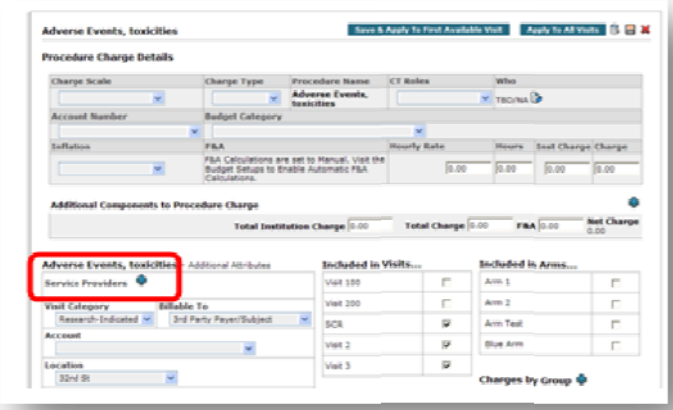
- Click **Apply to All Visits**
- Click **Close**.



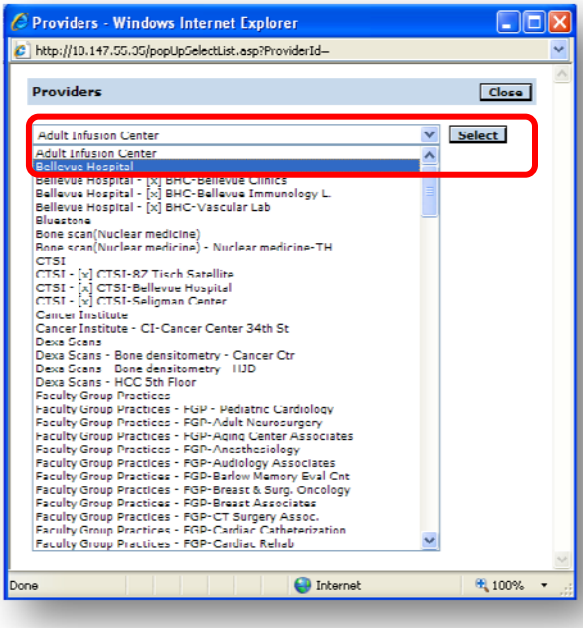
Add a Provider

To add a Provider:

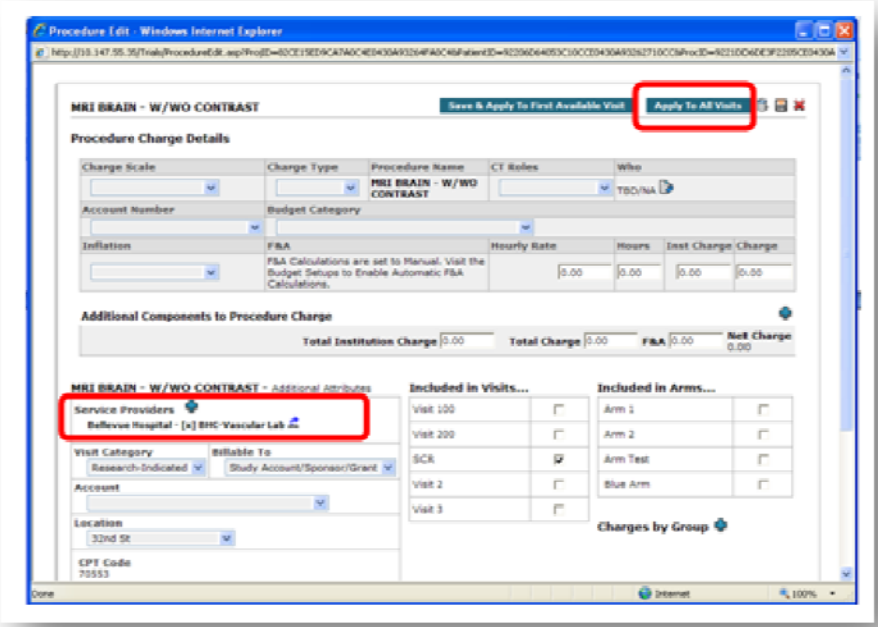
- Click on the procedure name for the visit.
- Locate the Service Providers area
- Click the **+** sign.



- Click the drop-own arrow to locate the provider name
- Click **Select**.



- Click **Apply to All Visits**.
- Click **X** to close.



Billable

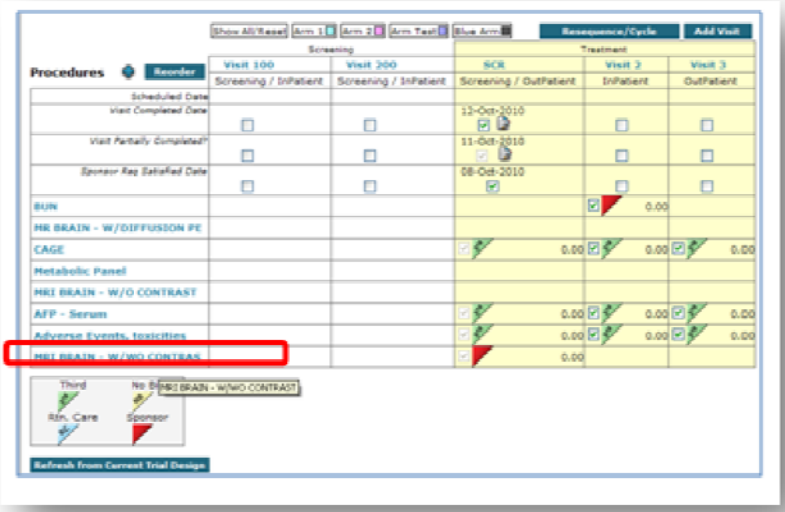
The **Billable To** field indicates who the charge should be billed to for a specific visit procedure.

Options available for the **Billable To** field are:

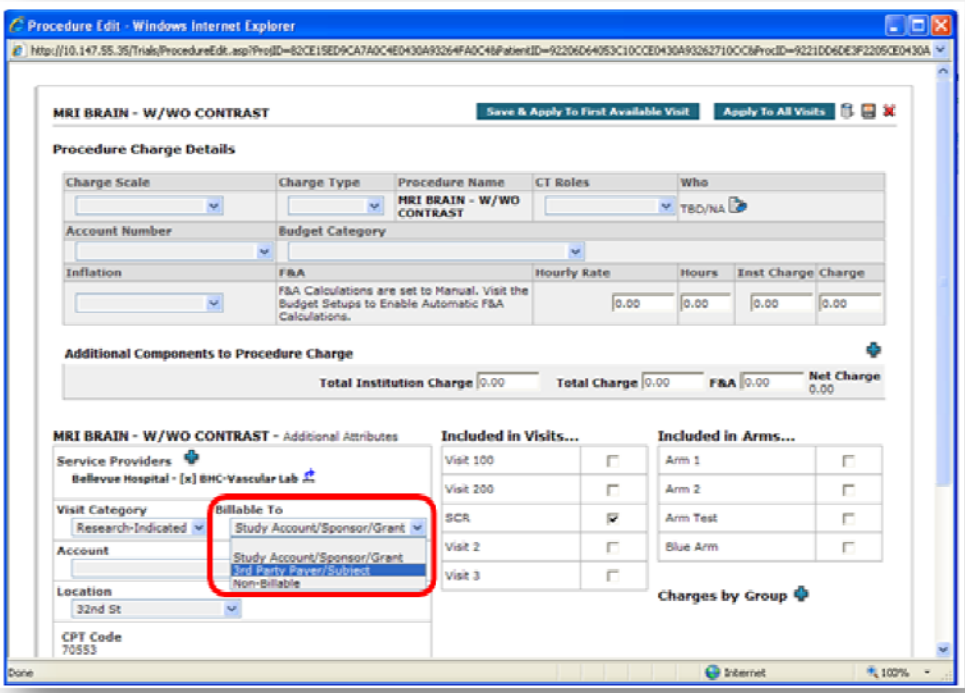
- **Study Account/Sponsor/Grant**
- **3rd Party Payer/Subject**
- **Non-Billable**

To add or change the **Billable To** field:

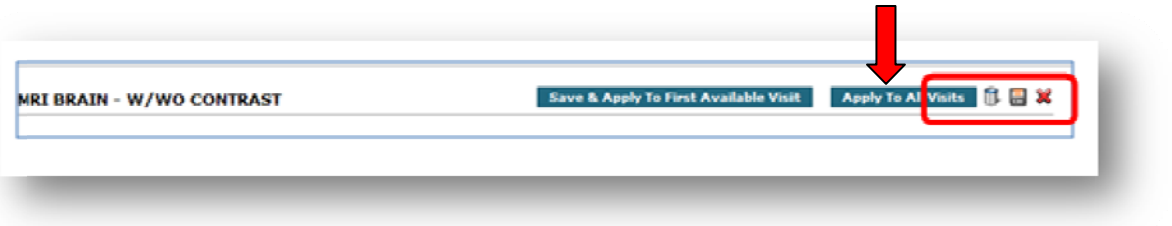
- Click on the specific procedure for the visit, such as **MRI BRAIN – W/WO CONTRAS**.



- Click the **Billable To** drop down arrow and select the correct **Billable to** option, such as 3rd Party Payer/Subject.



- Click **Apply to All Visits** then click **X** to close.

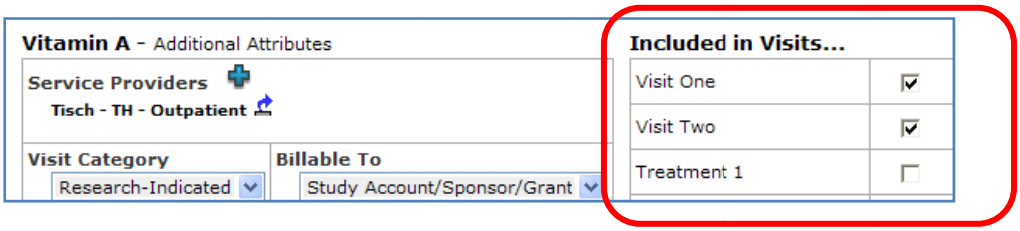


Eliminating or Adding a Procedure from a Visit

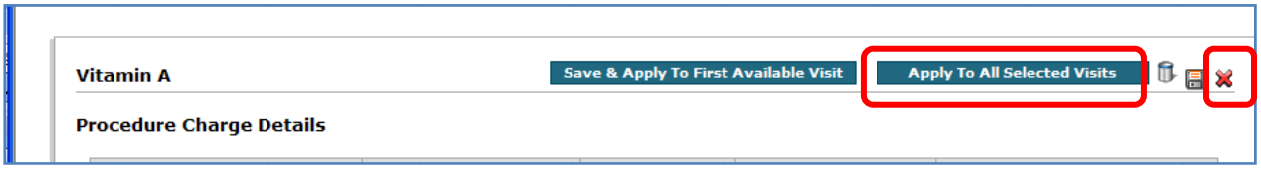
Important: At the Visits screen, eliminate procedures first as applicable. Once a ticket is completed, procedures can no longer be added to the visit.

In the Procedure screen:

1. Uncheck the visit to which the procedure no longer applies or check the Visit to which the procedure applies.



2. Click **Apply to all visits**, then **Close**.



How to Mark a Visit as Completed (Creating a Ticket)

The **Visits** screen is where you mark off that a participant has actually come in and either partially or fully completed their scheduled visit.

- **Important**: You must mark your visits complete on either the day when they occur or one or more day(s) before. In order to comply with the trials billing requirements, the Office of Clinical Trials requires that you mark your visits complete either ahead of time (the day before) or on the day that the visit occurs.

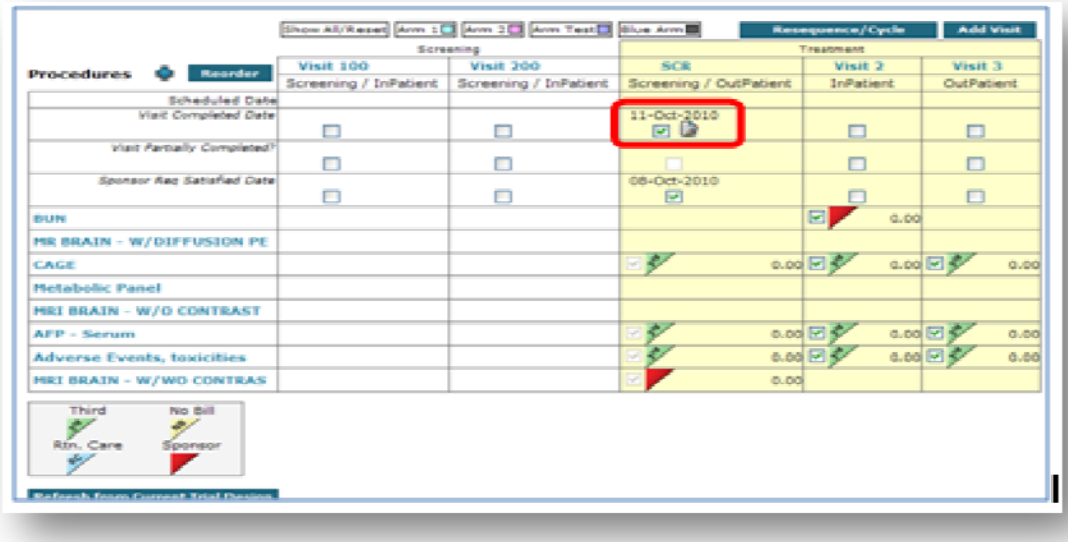
- If the participant cancels a pre-marked visit, you have until that scheduled evening of the visit to return to CTMS and "uncheck" the visit.

- If you miss marking off a visit, you should call your OCT contact to let them know of the late visit recording.

Visit Completed

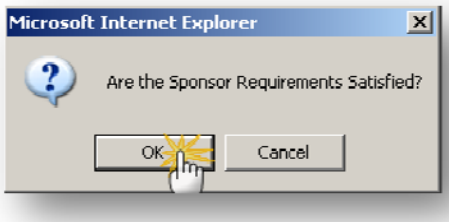
The Participant came and did everything that was required, and the visit was completed.

- Check off the **Visit Completed** checkbox if all of the procedures for the visit were done.



A message pop-up will appear, asking if the sponsor requirements were met.

- Click **OK** or on some browsers click **Yes**, in response to the pop-up screen stating the sponsor requirement for this visit were completed.



The date completed will be automatically generated using today's date.
Open the Research Encounter Ticket and confirm the information as correct.

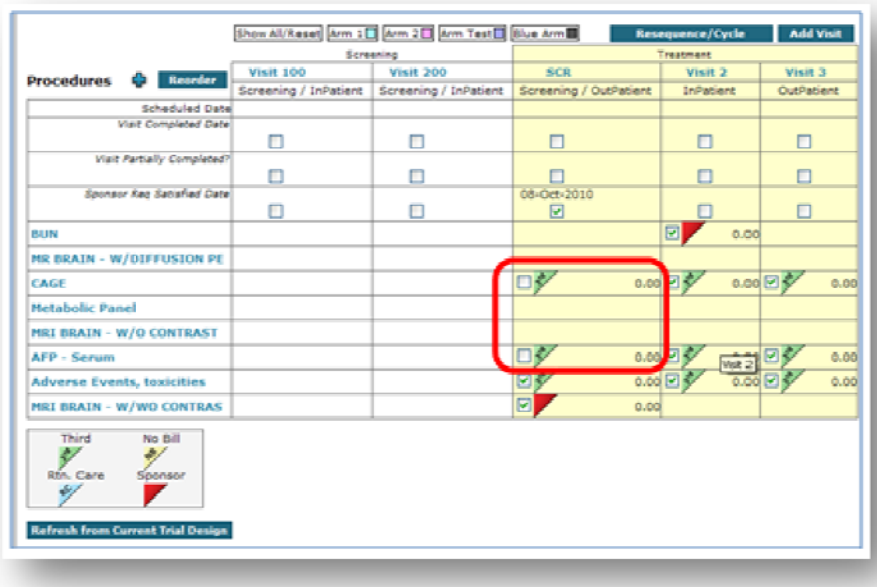
- The ticket is given to the Patient and emailed/faxed/or printed to the service provider.

Visit Partial Date of Service

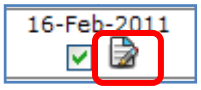
CTMS allows you to complete 2 tickets for a visit.
If all of the procedures for a visit are completed in 2 days, then you will need to do the following:

First Day

1. For the first day, uncheck the procedure(s) services that were not completed using the checkboxes in the visit column.



2. Click the **Visit Partially Completed?** Checkbox provided.



Click on the ticket to confirm the Information as correct.
Provide the ticket to the **Participant** and to the **Service Provider.**

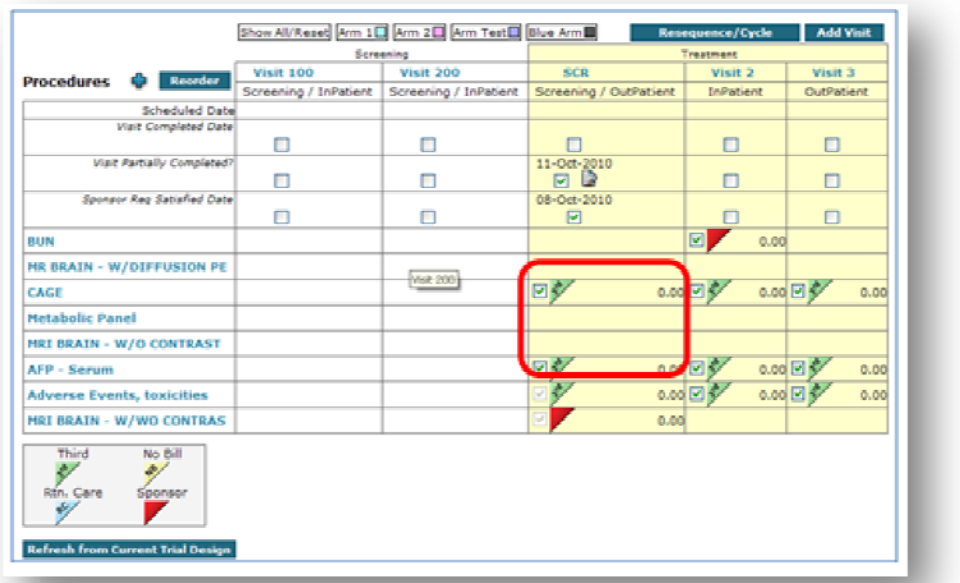
Second Day

These steps are for the second day of the visit when **all** procedures have been completed.

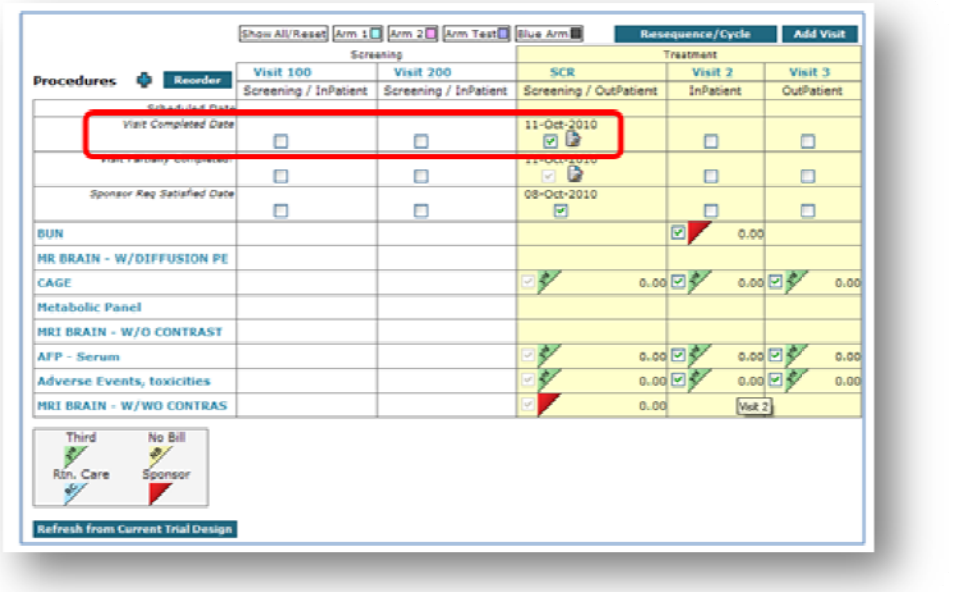
For example, the participant came in for the first day with procedures Adverse Events, toxicities and MRI BRAIN – W/WO CONTRAS completed.
During the second day, the participant had the remaining procedure(s) done:

- For the second day, click checkboxes for the remainder of the procedure(s) to indicate done.

  All procedures should be completed the second day.

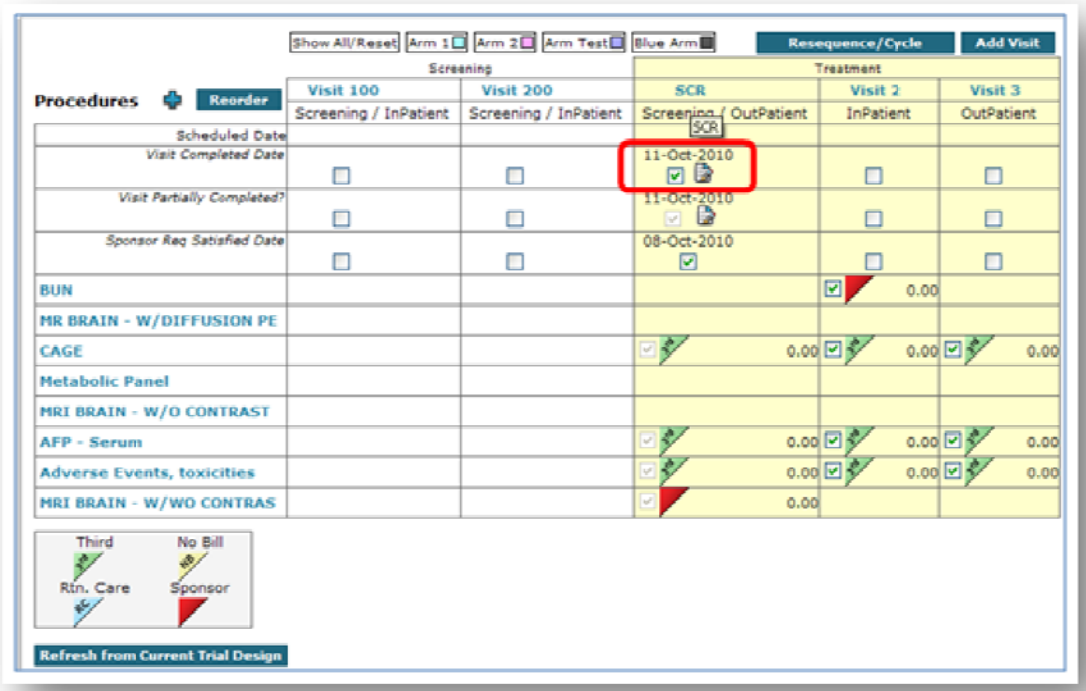


- Check off the **Visit Completed** checkbox.



- A message pop-up will appear, asking if the sponsor requirements were met.
- Click **Yes**.

  The date completed will be automatically generated using today's date.



- Important: Click the Encounter Report Ticket icon and confirm the ticket for completeness and accuracy.

- Reminder: Present the ticket to the Participant and the Service Provider. See the Research Encounter Ticket below.

Research Encounter Ticket

The InfoEd CTMS module generates an **Encounter Ticket** for your participants for each visit you check off as **Completed** or **Partially Completed**.

This ticket details the location(s) and procedures that a participant will undergo during a visit. It is called an **Encounter Report**.

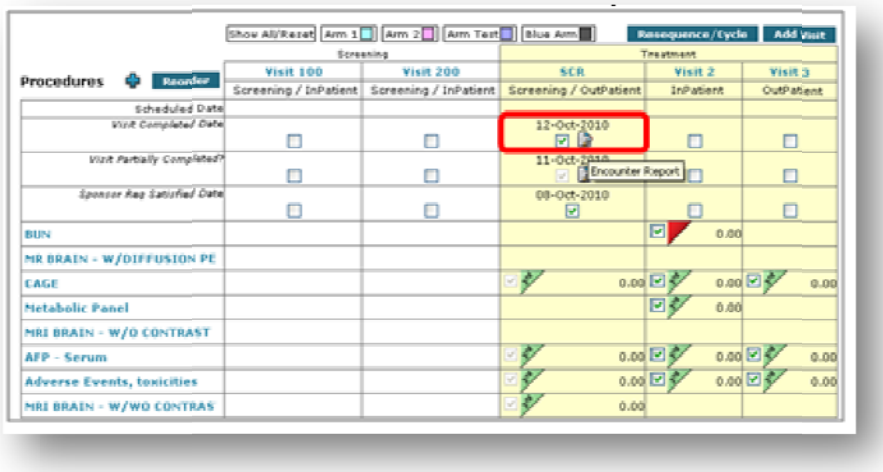
This ticket should be printed and provided to the participant to take with them when they get the procedures done.

Opening Tickets

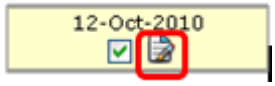
It is the Coordinator responsibility for the ticket as correct. To get to the visit ticket, follow these steps:

- Open your study in CTMS
- Open the Participant whose ticket you wish to print.
- Go to the Visit section for that participant.

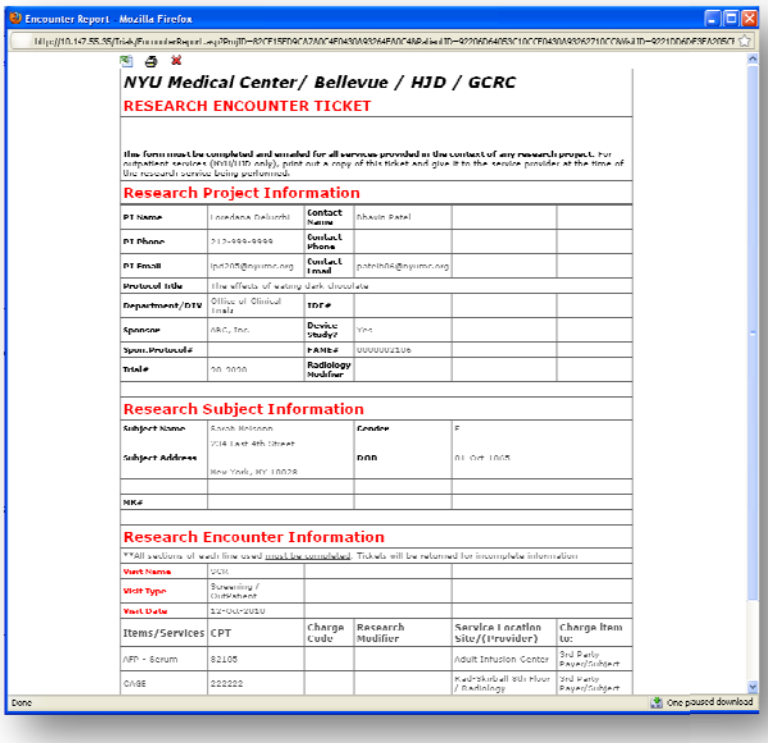
  For example, your Participant has completed the visit and the visit was marked as complete.



- Click the **Encounter Report** Ticket icon to the right of the Visit checkbox.



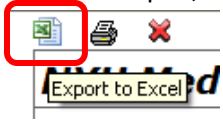
  The Encounter Report window pops up.



Printing Tickets

- Open the applicable study and participant.
- Go to the Visit section for that participant.
- Click the Encounter Report Ticket icon to the right of the Visit checkbox.
- Select **Print** via the upper left-hand corner icon.
- Click **Close** to close the window .

Exporting Ticket to Excel

- When the Research Encounter Ticket is open, click the **Export to Excel** icon to export the ticket in Excel spreadsheet format. 

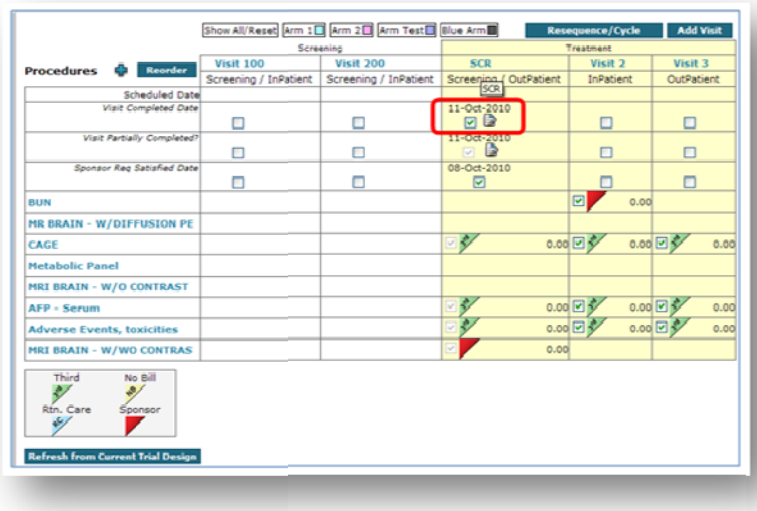
Changing the Visit Date of Service

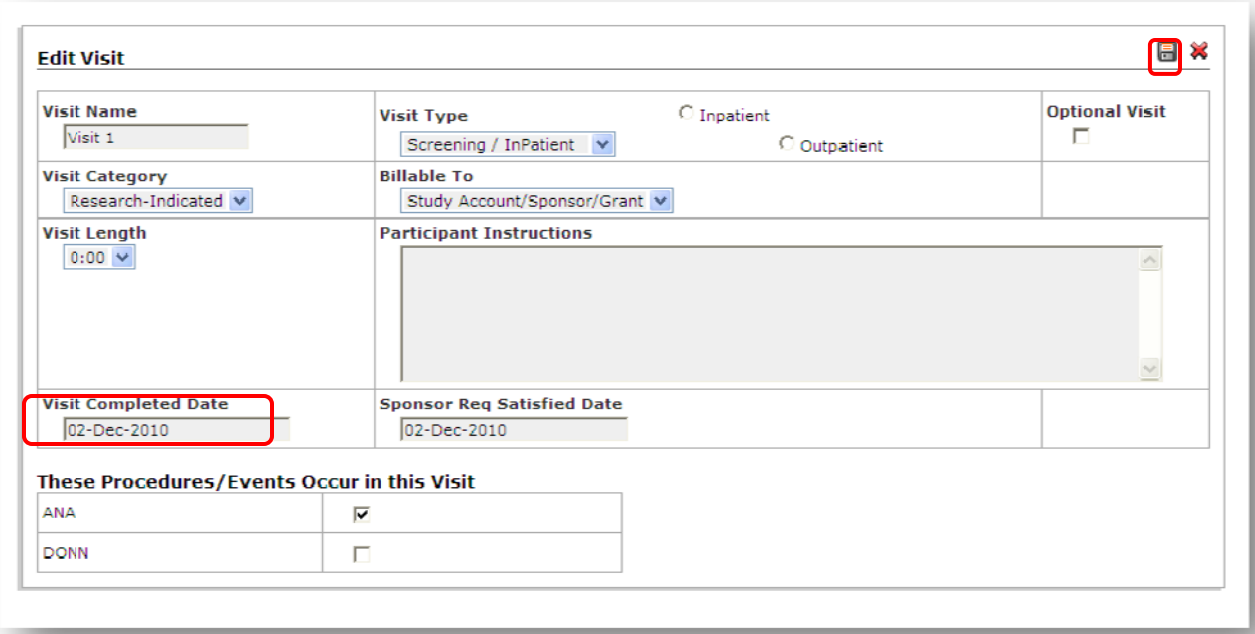
If the Visit date is any other day other than the current day such as when procedures are completed in two dates, it is necessary to change the Visit Date of Service.

You are able to change the Visit Completed Date and the Sponsor Req Satisfied Date.

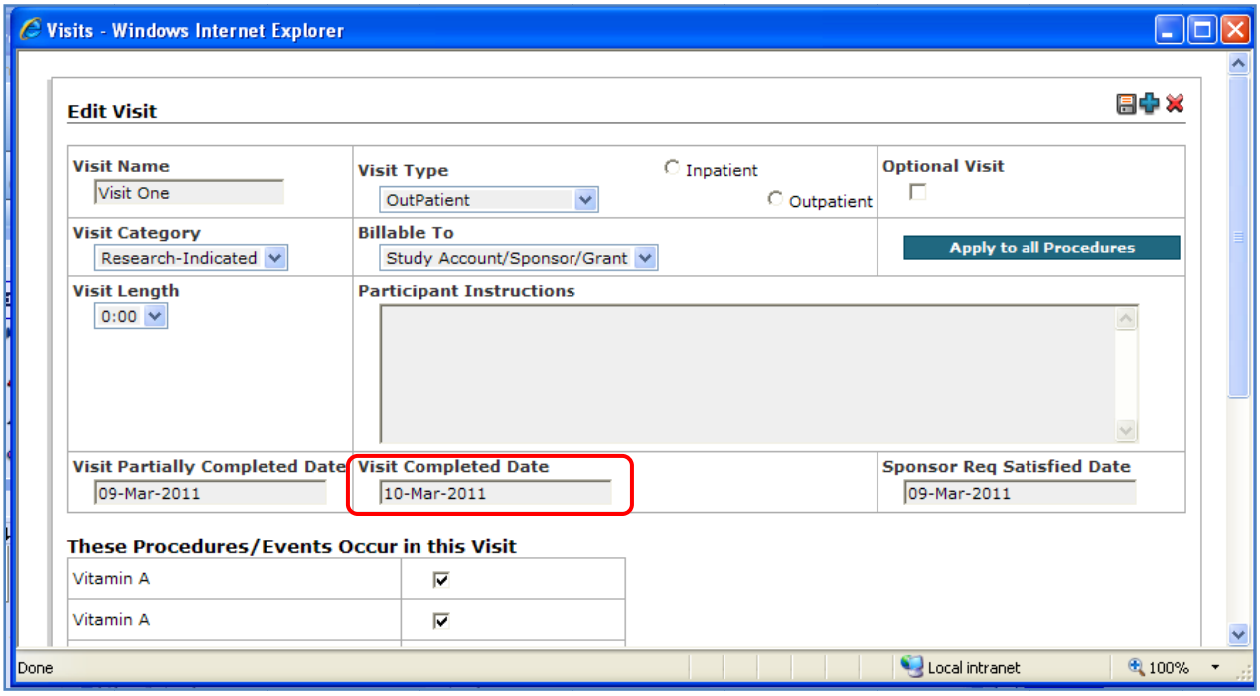
- Click on the **Visit Name** hyperlink at the top of the visit column.

For example, if the Participant came the day before the date entered in the Visit, change the date by clicking on the visit name at the top of the column:



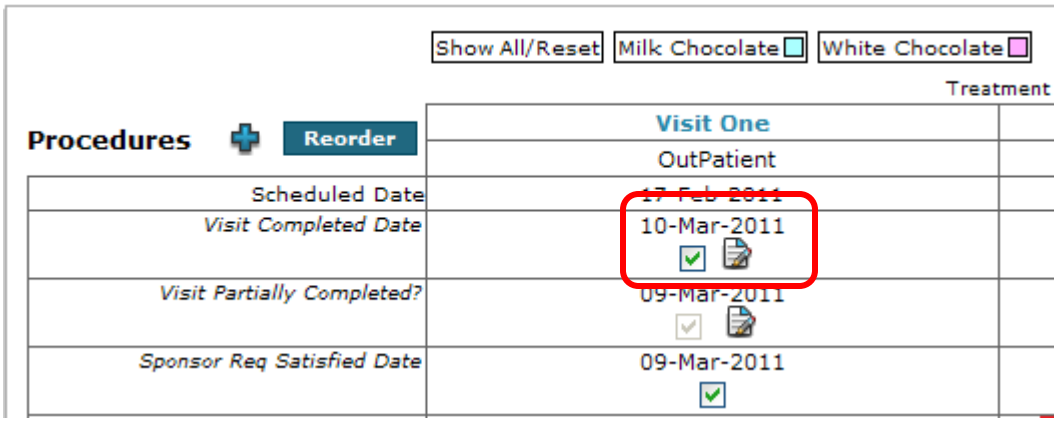


- Change the **Visit Completed Date** only.
- Click **SAVE** in the upper right corner. The date is now one day earlier.



- Type the correct Visit Completed Date.
- Click **Save**.

- Click **Close**.

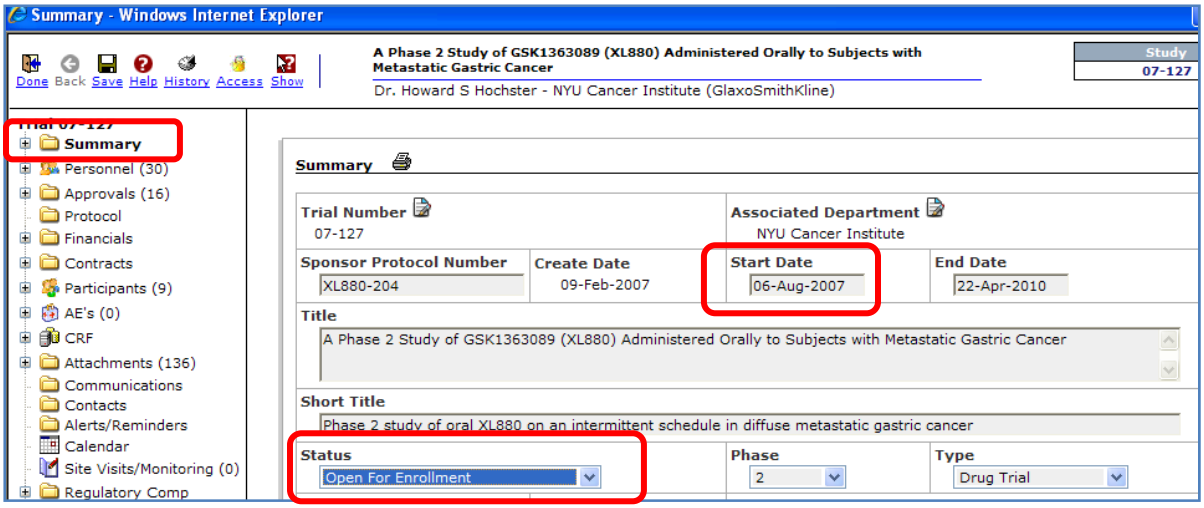

Show All/Reset
Milk Chocolate
White Chocolate
Treatment
Procedures
Reorder
Visit One
OutPatient
Scheduled Date
17-Feb-2011
Visit Completed Date
10-Mar-2011
Visit Partially Completed?
09-Mar-2011
Sponsor Req Satisfied Date
09-Mar-2011

Appendix

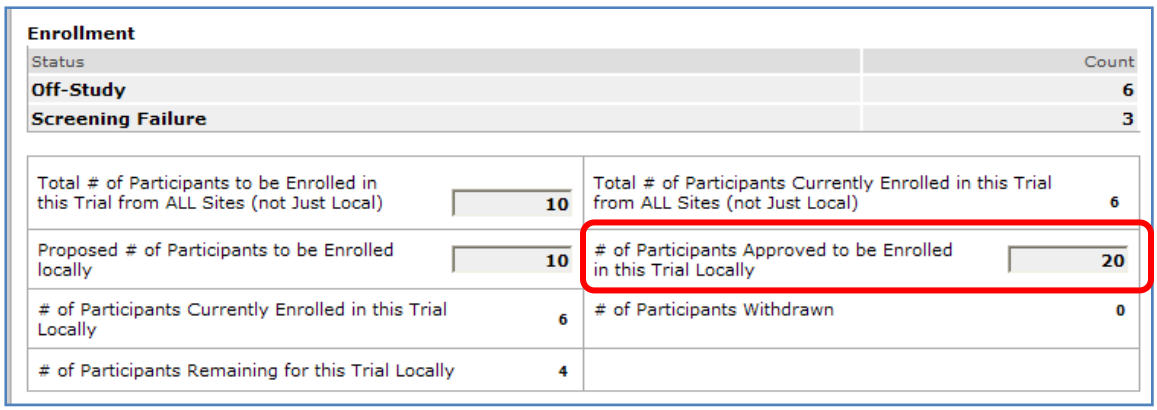
A. What Needs to be Completed in order to Add Participants

In order to Add Participants to your Trial, the following must be entered in the **Summary Screen**.

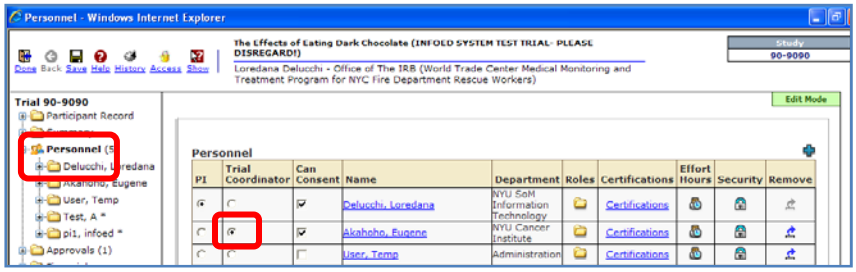
- Start Date
- Status as **Open for Enrollment**



- Total participants greater than the number of participants


Enrollment
Status
Count
Off-Study
6
Screening Failure
3
Total # of Participants to be Enrolled in this Trial from ALL Sites (not Just Local)
10
Total # of Participants Currently Enrolled in this Trial from ALL Sites (not Just Local)
6
Proposed # of Participants to be Enrolled locally
10
# of Participants Approved to be Enrolled in this Trial Locally
20
# of Participants Currently Enrolled in this Trial Locally
6
# of Participants Withdrawn
0
# of Participants Remaining for this Trial Locally
4

- In the Personnel screen, the Trial Coordinator Contact must be entered.



B. Contracts/Agreements Statuses

Status	Definition	Used by
ICF = CTA - CRMC	ICF = CTA - used when ICF/CTA match and when requested modifications to ICF based on CTA are submitted to IRB for approval	CRMC
ICF Needs Reconciliation with CTA - CRMC	ICF-CTA language mismatch - RMC requests SC make necessary amendments	CRMC
Budget - Finalized Pending Contract	When budget and payment terms are finalized, but contract language is still being negotiated	CRMC
Budget - Initial NYU Review	1st review/mark up by NYU taking place	CRMC
Budget - Negotiation at OCT	Budget is at a middle negotiation and is currently with NYU	CRMC
Budget - Negotiation at PI/Study Team	Budget is at a middle negotiation and is currently with PI/Study team	CRMC
Budget - Negotiation at Sponsor	Budget is currently with the sponsor, any point after the initial mark up has been done by NYU and prior to finalization	CRMC
Budget - Waiver of Usual or Standard Fees	When any fee or usual budgetary item is waived. Comments should note what has been waived and by whom	CRMC
Budget - Waiver Requested	When a fees waiver is requested. Comments should note what is being requested and who is reviewing the request	CRMC
CTA - BRANY CTA and Partially Executed Study Memo received by NYU	When OCT receives fully executed CTA and Partially Executed Study Memo from BRANY - NYU signatures on Study Memo needed	CS

CTA - BRANY CTA with NYU for approval	When NYU receives near-final CTA and/or Study Memo from BRANY for approval prior to execution.	CS
CTA - BRANY negotiating	CTA is in negotiation by BRANY.	CS
CTA - Final CRMC Review	CTA (language/budget/payment terms) has been finalized and executable copies are being reviewed by CRMC prior to Directors signature	CRMC
CTA - Final CS Notes and Exceptions	For CS to document final notes and exceptions - including any waivers related to contract language	CS
CTA - Final CS Review	CTA (language/budget/payment terms) has been finalized and hard copies are being reviewed by CS prior to Directors signature	CS
CTA - Finalized Pending Budget	When contact language finalized, but budget is still being negotiated	CS
CTA - Fully Executed Agreement	When OCT receives fully executed (signed by all parties) CTA	CS
CTA - Initial Review	Initial contract language mark up by NYU taking place	CS
CTA - Language and Budget Finalized - Awaiting Executable Copies	Awaiting for executable copies of final CTA from sponsor	CS
CTA - Negotiation at NYU	CTA is at a middle negotiation and is currently with NYU	CS
CTA - Negotiation at Sponsor	CTA is currently with the sponsor, any point after the initial mark up has been done by NYU and prior to finalization	CS
CTA - Partially Executed CTA received by NYU	Hard copies of finalized CTA signed by sponsor - NYU signatures needed	CS
CTA - Signed by Director	Director chooses this when they sign the CTA = OCTs contracting end date	OCT Dir
CTA - Waiver of Liability/Other terms	When a waiver of indemnification or standard subject injury language is granted. Comments should note what was approved and by whom	CS
CTA - Waiver Requested	When a waiver of indemnification, standard subject injury language, or other term is requested. Comments should note	CS

	what is being requested and who is reviewing the request	
CTA - With OCT Director for Signature	When the CTA is sent to the OCT Director for signature	CS/CRMC
CTA - With PI for Signature	When the CTA is sent to the PI for signature	CS
CTA - With Sponsor for Signature	When the CTA is sent to the sponsor for signature	CS
In Initial Review by NYU	Have received all items needed for initial review - contract template, Budget template, R#, protocol, sponsor contact information, dept "GO". This will generally be the 1st status seen in the contracts folder	CRMC
Pending Initial Review	Have not received all items needed for initial review - should list what is missing	CRMC
Transferred to Another Contracting Office	When negotiation transferred after Day 0 documented	CS/CRMC
Withdrawn/Never Finalized	CTA (language and/or budget) never finalized or withdrawn (closed before site initiation)	CS/CRMC

C. CTMS Trial Statuses

These are various statuses available in CTMS, and what they mean. They are presented in approximately the order of a study's approval process/lifecycle.

Pending

Pre-PRMC approval - No regulatory or contractual work has begun yet.

Under Review

PRMC approved - initial work has begun from a regulatory, financial, and/or contractual perspective. Multiple approval groups need to review and give their approval to the study before it can be opened to enrollment.

Open to Enrollment

All required approvals have been received and documented. This includes all institutional and group approvals, the grant or contract has been executed, the study visits have been built and CTMS is ready to receive enrollment data.

Disapproved

Something or some group has not OK'd the project and no further reconciliation is being attempted to open this study at this time.

Suspended

A research study is stopped or suspended by the IRB for regulatory, human subject, or other concerns.

Enrollment on Hold

Any reason a trial is put on hold other than IRB specific. Specifically, it would be because of PI or sponsor issues that would stop enrollment however it would not imply an IRB-imposed suspension.

Terminated

This project enrolling was terminated by PI or Sponsor prior to completing its required enrollment criteria.

Closed

This study completed its contracted enrollment, all follow ups are completed, all data queries are solved, all financials have been accounted for, and the study is closed out in the IRB.

Closed - In Long Term Follow-up

This study is closed to enrollment and has a potentially infinite long term follow up phase with no end. Patients are followed at some specified time increment for mortality until end of life.

Closed to Enrollment

This study is closed to new enrollment but ongoing enrolled subjects still have visits to complete or data analysis is ongoing. Study is still "opened" in the IRB and continuations need to be completed yearly.

Withdrawn

Withdrawn is used when a Principal Investigator decides he/she no longer wishes to submit a research study for review but withdraws it from submission. The decision has been made not to pursue opening a project PRIOR to it being open for enrollment. The review decision would show Withdrawn.

Exempt

IRB Approved Projects accepted as Exempt in the IRB and do not have any billing requirements that would necessitate a billing plan submission to the OCT.